

On the Ethical Implications of Personal Health Monitoring

A Conceptual Framework for Emerging
Discourses

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Abstract

Recent years have seen an influx of medical technologies capable of remotely monitoring the health and behaviours of individuals to detect, manage and prevent health problems. Known collectively as personal health monitoring (PHM), these systems are intended to supplement medical care with health monitoring outside traditional care environments such as hospitals, ranging in complexity from mobile devices to complex networks of sensors measuring physiological parameters and behaviours. This research project assesses the potential ethical implications of PHM as an emerging medical technology, amenable to anticipatory action intended to prevent or mitigate problematic ethical issues in the future.

PHM fundamentally changes how medical care can be delivered: patients can be monitored and consulted at a distance, eliminating opportunities for face-to-face actions and potentially undermining the importance of social, emotional and psychological aspects of medical care. The norms evident in this movement may clash with existing standards of 'good' medical practice from the perspective of patients, clinicians and institutions. By relating utilitarianism, virtue ethics and theories of surveillance to Habermas' concept of colonisation of the lifeworld, a conceptual framework is created which can explain how PHM may be allowed to change medicine as a practice in an ethically problematic way. The framework relates the inhibition of virtuous behaviour among practitioners of medicine, understood as a moral practice, to the movement in medicine towards remote monitoring.

To assess the explanatory power of the conceptual framework and expand its borders, a qualitative interview empirical study with potential users of PHM in England is carried out. Recognising that the inherent uncertainty of the future undermines the validity of empirical research, a novel epistemological framework based in Habermas' discourse ethics is created to justify the empirical study. By developing Habermas' concept of translation into a procedure for assessing the credibility of uncertain normative claims about the future, a novel methodology for empirical ethical assessment of emerging technologies is created and tested. Various methods of analysis are employed, including review of academic discourses, empirical and theoretical analyses of the moral potential of PHM. Recommendations are made concerning ethical issues in the deployment and design of PHM systems, analysis and application of PHM data, and the shortcomings of existing research and protection mechanisms in responding to potential ethical implications of the technology.

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Glossary

AMI	Ambient Intelligence
AT	Assistive Technology
BP	Blood Pressure
CCG	Clinical Commissioning Group
CCSR	Centre for Computing and Social Responsibility
CCTV	Closed-circuit Television
COPD	Chronic Obstructive Pulmonary Disease
CSO	Civil Society Organisation
DH	Department of Health
DMU	De Montfort University
DP	Data Protection
ECG	Electrocardiography
ETICA	Ethical Issues of Emerging ICT Applications (FP7 research project)
EU	European Union
FP7	7 th Framework Programme
GA	Grant Agreement
GMC	General Medical Council
GP	General Practitioner
GPS	Global Positioning System
HRE	Human Research Ethics
ICT	Information and Communication Technology
iTA	Interactive Technology Assessment
NHS	National Health Service
NICE	National Institute for Health and Clinical Excellence
NRES	National Research Ethics Service
OC	Organisational Codes
PHM	Personal Health Monitoring
PP	(The) Precautionary Principle
RCT	Randomised Clinical Trial
REC	Research Ethics Committee
RFID	Radio-frequency Identification
R&D	Research & Development
SC	Substantive Codes
TA	Technology Assessment
TCA	Theory of Communicative Action
Ubicomp	Ubiquitous Computing
UK	United Kingdom
WSD	Whole System Demonstrator

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1 Chapter 1: Introducing the Project and Associated Research

1.1 Introduction

Recent years have seen an influx of medical technologies capable of remotely monitoring the health and behaviours of individuals to detect, manage and prevent health problems (Schmidt & Verweij 2013). Known collectively as ‘Personal Health Monitoring’, these systems are intended to supplement medical care with health monitoring outside traditional care environments such as hospitals, and range in complexity from single-sensor mobile devices to complex networks of sensors measuring physiological parameters and behaviours.

Development has been primarily driven by the perceived medical, social and economic benefits for patients associated with health monitoring at home (Neild et al. 2004; Gaul & Ziefle 2009; Bowes et al. 2011; Palm 2011; Ure et al. 2012), and the perceived need to supplement existing medical resources to address demographic trends towards aging populations in developed countries (United Nations 2007; United Nations 2008; Population Reference Bureau 2012) via technological means (Rigby 2007, p.352; British Medical Association 2008; OECD 2010; Remmers 2010; Sadri 2011).¹ Systems are being developed for a range of demographics (see: Chapter 2), with many targeting the elderly and chronically ill.

PHM has the potential to facilitate ethically problematic medical interactions as the lives of patients outside GP offices and hospitals are subject to medical scrutiny for the sake of identifying, categorising and managing health conditions (cf. Lyon 2003). A sense of privacy and self-determination in daily life may be lost (Remmers 2010), as PHM reminds the user of a medical condition (Courtney et al. 2007; Light 2010). Face-to-face interactions between patients and providers may be reduced as care is increasingly provided remotely, while vast amounts of sensitive health data are captured and processed, future implications of which cannot be predicted with certainty.

Existing protection mechanisms may be insufficient to respond to ethical issues raised by PHM, as policies and legislation are often not updated frequently enough to respond to problems emerging from technological innovation, creating a ‘policy vacuum’ (Moor 1985). In the field

¹ The assumption that an ageing demographic necessarily places greater demands on healthcare resources, which fuels the perception that healthcare systems must adapt to demographic trends, requires a correlation between age and demand to be viable. Such a correlation is not self-evident (Arrison 2011). Whether or not it can be proven, the influence of this questionable belief on medical ICT development is broadly evident (e.g. Rigby 2007, p.352; British Medical Association 2008; OECD 2010; Remmers 2010; Sadri 2011).

of medical information and communication technologies (ICT) this is particularly worrying due to the strong protections typically granted to data about bodies or health. Personal health data is treated as a particularly 'sensitive' category of data in data protection (DP) measures in the United Kingdom (UK) and European Union (EU) (European Parliament 1995; UK Department of Health 1998), deserving of greater protection and limitations of use to protect the privacy rights of individuals. PHM presents unprecedented opportunities for the collection, analysis, mining and sharing of personal health data (Mittelstadt, Fairweather, et al. 2013), so questions must inevitably be asked about the implications for the privacy of patients.

PHM is designed to operate within the private sphere, being worn on the body or installed in 'personal spaces' such as the home. The private lives of users can be digitised, recorded, stored and analysed, creating novel opportunities for data sharing, mining and social categorisation (cf. Lyon 2003). New connections can be created between areas of private life traditionally outside the scope of health and health care (Bowes et al. 2011). By design, PHM broadens the scope of health and medicine by allowing for various parameters of private life to be monitored in the pursuit of better health. The quantity and quality of information available to clinicians and medical institutions in delivering care increases, and alternative means for care delivery are established; however, these advances are not necessarily beneficial for patients.

These observations merely hint at what is known of the ethical implications of PHM, which can be seen to raise questions about the appropriate relationships between humans, technology and the natural world in pursuit of better health and longer life. With the potential to change how humans relate to each other under the auspices of health and medical care, PHM can be said to have 'moral potential', or the potential to contribute to situations in which divergent conceptions of the 'good' life or 'right' actions come into conflict (see: Section 3.1.1).

Interest in PHM can be seen throughout the EU in a growing body of academic research (see: Chapter 2), systems in development (Empirica & WRC 2010), and interdisciplinary research projects (Gök et al. 2013, p.68). As an emerging technology with the potential to fundamentally change the delivery of medical care through the creation, analysis and transmission of data about the lives, environments, bodies and behaviours of patients, the opportunity remains to proactively respond to the potential issues of a PHM-enabled future. However, anticipatory action requires first understanding the potential ethical issues raised by

PHM. Two recent EU research projects looking at the ethical implications of PHM and similar emerging technologies can help to begin to explain the technology's vast moral potential. These projects helped direct the scope of research in this thesis, and further justify why it is necessary to research the ethical implications of PHM.

1.2 Associated Research: PHM-Ethics and ETICA²

As novel technologies are developed and implemented in various contexts of use, normative issues accrue which must be addressed at local, national and international levels. Within the EU, this need for 'ethics governance' is met through a variety of approaches including research, policy, and ethics review committees. The 7th Framework Programme (FP7), sponsored by the European Commission, placed calls research projects which would develop approaches for ethical, social and legal assessment of emerging technologies to address the limitations of governance.

PHM-Ethics (GA 230602) and ETICA (Ethical Issues of Emerging ICT Applications, GA 230318) were among the projects that responded to these calls. PHM-Ethics directly addressed ethical implications of Personal Health Monitoring through multidisciplinary research. ETICA was a sister research project to PHM-Ethics, which focused on the ethical implications of a broad set of emerging ICTs, which included technologies similar to PHM. Through a shared orientation towards policy and development, the two projects provided concrete recommendations and practical tools for ethics governance based upon interdisciplinary methodologies incorporating theoretical and empirical approaches. In the process, PHM was categorised by technological features to assist in ethical, social and legal assessment of different applications. Methodological challenges faced in the ethical assessment of emerging technologies were also addressed.

In contrast to prior procedural governance approaches (Goujon & Flick 2011), neither project sought to provide a comprehensive list of ethical issues and solutions for emerging ICTs or PHM. Rather, each sought to identify potential ethical issues, with recommendations for further discourse between stakeholders for future context-specific governance. The projects developed methodologies for the incorporation of ethical, social and legal methodologies into innovation and governance. In both projects EU legislation and approaches to ethics

² This section contains passages taken from a previously published collaborative work (Mittelstadt, Stahl, et al. 2013). All such passages are the original work of the researcher. For the full text, see: Appendix A17.3.

governance (e.g. ethics review committees, FP7 programmes, Technology Assessment) were critically reviewed to identify procedural gaps and limitations to overcome through development and implementation of the assessment methodologies (PHM Ethics Consortium 2011a; Szekely et al. 2011). The reviews revealed both short and long-term problems related to context-sensitivity, reliance upon expert opinions in governance, ethical “blind spots” (PHM Ethics Consortium 2012) which preclude consideration of emerging ethical issues, and various legal challenges to be overcome in implementing PHM and emerging ICT, such as liability law reform (Stahl 2011a, p.5; PHM Ethics Consortium 2012).

ETICA (Stahl 2011a, p.4) and PHM-Ethics both focused on ‘high-level’ technologies, and based ethical analysis on general defining features of each technology as opposed to specific applications. A distinction was defined between technologies, artefacts and applications in ETICA, seen as a spectrum proceeding from general to specific (Stahl 2011a). At the most specific, applications are systems bound by a fixed characteristic of their context of use, including specific uses, methods of interaction, characteristics of users and aspects of the location of use (Brey 2011, p.21). To use ‘smart homes’ as an example: PHM is a technology, sensors installed in the home are artefacts, and fall detection combining data from various sensors is an application. The technology level focus of both projects was appropriate considering the early stage of development and implementation at which PHM currently exists: proactive governance, such as broad EU regulatory frameworks, is still feasible. Furthermore, conceptual frameworks are still required within which the potential ethical implications of PHM may be identified and understood.

1.2.1 PHM-Ethics³

The main aim of PHM-Ethics was to “conduct scientific interdisciplinary research to analyse the dependencies between ethics, law and psychosocial sciences in personalised health monitoring in relation to the major types and steps of this very dynamic part of IT-development from a European perspective” (PHM Ethics Consortium 2012, p.8). PHM was defined as “all technical systems collecting, processing, and storing data linked to a person. It allows monitoring parameters of that person and can lead to health-related information of that person” (PHM Ethics Consortium 2011b, p.6). An integrated European approach to the combined regulation

³ Further information, deliverables and dissemination activities can be found on the project’s web-site: <http://ethics.p-h-m.org/>.

of ethical, philosophical, legal and psychosocial constraints was developed (PHM Ethics Consortium 2012) between several European partners.⁴

Emphasis was placed on the creation of a reflexive, open-ended PHM-Ethics ‘toolbox’ for ethical, legal and psycho-social assessment of emerging PHM applications in future contexts. An assessment methodology was developed to meet this goal consisting of five components:

1. **Dependencies Map:** A multi-layered, complex network of relationships illustrating dependencies and relationships between stakeholders involved with PHM (e.g. government, clinicians, policy makers, patients).
2. **Taxonomy:** A classification system which categorises PHM technologies and applications representing the state of the art in PHM. Categories with similar characteristics were created to make distinctions between similar technologies.
3. **Psychosocial Assessment Module:** An integrated module for psycho-social health technology assessment. It consists of a map highlighting selective psychosocial issues of relevance when applied to a PHM application. It covers various domains of technology perception and psychosocial outcome criteria.
4. **Ethical Assessment Module:** A module for ethical evaluation of existing and upcoming PHM applications. Ethical values and principles are put into perspective within PHM, raising questions in the fields such as privacy, autonomy, freedom of choice and justice.
5. **Legal Framework:** A legal report that describes EU legislation relevant to telemedicine and health monitoring. It takes into account the consequences of recent decisions by the European Court of Justice important for PHM, regarding privacy and reimbursement of monitoring systems. Limitations and gaps in regulation and governance schemes are identified, along with differences in ethical constraints established in EU directives and national legislation (PHM Ethics Consortium 2012, pp.8–9).

Each component can be viewed as an assessment tool to be applied to specific PHM applications in future contexts. The tools are complementary in the sense that results from one can be used to inform application of the others. For example, the modules allow for assessment at multiple levels of the taxonomy, guided by the interrelationships identified in the dependencies map. The taxonomy and dependencies map will be updated in light of future PHM developments (PHM Ethics Consortium 2012).

PHM-Ethics consisted of three phases, the first of which identified ethical, psychosocial and legal implications of emerging PHM applications through a descriptive literature review and empirical research (PHM Ethics Consortium 2012, p.12). The Dependencies Map and

⁴ Project partners: De Montfort University (UK), Ernst-Moritz-Arndt-University Greifswald (Germany), Linköping University (Sweden), Law Firm Callens (Belgium), University Medicine Göttingen (Germany), National Institute of Health and Medical Research (France), University Utrecht (Netherlands).

Taxonomy were developed from the findings. The second phase was dedicated to the assessment of PHM from ethical, legal and psycho-social perspectives. Assessment tools from these perspectives were developed and validated (PHM Ethics Consortium 2012, p.12). The third phase involved disseminating the developed methodology through validation workshops and a dissemination conference (PHM Ethics Consortium 2012, p.13).

A reduction in the time between development, ethical assessment and implementation is expected if the PHM-Ethics methodology is adopted by EU policy-makers and industry. Facilitation of a proactive approach to ethics governance, in which context-sensitive participatory assessment occurs simultaneously with development, is therefore the overall goal of PHM-Ethics. The developed tools assist in both identifying and responding to emerging ethical issues of PHM through engagement of stakeholders in these processes. Furthermore, a foundation is created for evidence-based policy-making through assessment with the PHM-Ethics toolbox.

1.2.2 ETICA⁵

The main objective of ETICA (Ethical Issues of Emerging ICT Applications) was to identify and evaluate emerging ICTs, potential applications, and their ethical implications. These activities, supported by critical evaluation of existing ethics governance in the EU, led to policy recommendations intended to facilitate proactive evaluation of the ethics of emerging ICTs (Stahl 2011a). The project included partners from universities in eight EU countries to ensure a broad European perspective.⁶

Review of ICT ethics literature led to the identification of eleven emerging technologies with predicted ethical relevance: Affective Computing, Ambient Intelligence (AMI), Artificial Intelligence, Bioelectronics, Cloud Computing, Future Internet, Human/Machine Symbiosis, Neuroelectronics, Quantum Computing, Robotics and Virtual/Augmented Reality. Of the identified technologies, AMI was closely related to PHM, with many potential applications in health monitoring (see: Section 2.3.2.4). Technologies were defined as “high-level socio-technical systems that have the potential to change the way humans interact with the world”

⁵ Further information on ETICA, including project deliverables and reports can be accessed via the ETICA website at: <http://www.etica-project.eu/>.

⁶ Project partners: De Montfort University (UK), VTT Technical Research Centre (Finland), Delft University of Technology (Netherlands), ForschungsZentrum Karlsruhe (Germany), University of Namur (Belgium), Steinbeis University Berlin (Germany), Eötvös Károly Public Policy Institute (Hungary), University of Lodz (Poland).

(Stahl 2011a, p.4). Emergence hinged upon current research and development, which indicates technologies that will be socially and economically relevant in the next 10-15 years. The emerging technologies are expected to overlap in future ICT developments, and are believed to exist in a hierarchical relationship (Stahl 2011a, p.15), in which ethical implications are shared across multiple technologies due to shared aims, audiences or technical characteristics. A methodology was described and validated within the project for identification and evaluation of the technologies as well as ethical, legal and social issues. Once identified, ethical issues of the eleven technologies were ranked by severity according to an interdisciplinary perspective.

Recommendations from ETICA were aimed towards policy-makers and industry which sought to improve ethics governance approaches (e.g. Goujon & Flick 2011; Stahl 2011a). While policy-makers were recommended to establish an environment in which participatory ethics governance is required and supported, industry, researchers and civil society organisations (CSOs) were encouraged to use the tools provided by policy-makers to undertake ethical assessment before implementation of emerging ICTs.

1.2.3 Ethical Assessment Methodologies

In PHM-Ethics a questionnaire based on interactive Technology Assessment (iTA) was created for ethical assessment of specific applications in future contexts of use. Technology Assessment (TA) comprises a family of approaches that aim to combine empirical research on likely consequences of technologies with normative insights (see: Section 7.3.1.6). Many 'flavours' of TA, including participative TA (van Eijndhoven & van Est 2002; Joss & Bellucci 2002) and iTA (Reuzel et al. 2001), involve laypeople in development and governance to improve the acceptability of emerging applications within specific contexts of use. In line with the aims of FP7 and PHM-Ethics, iTA is intended to improve the ethical acceptability of emerging PHM applications by providing a way for users to influence innovations at an early stage (PHM Ethics Consortium 2011c), perhaps reducing the time and appearance of ethical issues between deployment and governance. The involvement of non-experts is also intended to reduce expert bias in ethical assessment (Reuzel et al. 2001) by giving laypeople an equal role.

The PHM-Ethics questionnaire asks stakeholders to identify and rank moral values and principles with regards to the specific use of PHM in which they are involved (PHM Ethics

Consortium 2011c). In contrast with iTA (Reuzel et al. 2001), stakeholders are not asked to engage in theoretical ethical analysis, meaning the concerns, values and principles raised by lay persons are left to be interpreted (within theoretical frameworks) by ethical experts (PHM Ethics Consortium 2011c, p.53). The ethical assessment methodology is therefore participatory in a limited sense by deferring theoretical analysis exclusively to ethical experts (PHM Ethics Consortium 2011c, p.53).

Restricting the participation of laypeople in ethical assessment hints at a broader limitation of the project's ethical assessment methodology. The PHM-Ethics approach is designed to improve governance and development, not to facilitate discourse between stakeholders beyond governance schemes once a technological application is actually deployed, although the taxonomy and initial list of ethical issues may be helpful in this regard. Ethical issues are experienced and given meaning by stakeholders in specific contexts (cf. Nissenbaum 2004; Musschenga 2005), yet the PHM-Ethics methodology does not contribute to discourse between all stakeholders beyond a single stage of governance. In practice this means discourse between stakeholders outside of governance schemes, such as those occurring between a patient and his general practitioner (GP), do not benefit directly from the project. This is not necessarily a weakness of the approach, but rather a gap in the contribution of the project, suggesting a need for further 'patient-oriented' research.

In ETICA, ethical assessment consisted of two phases. In the first, ethical issues were identified through analysis of the matrix of emerging applications. Technology-level analysis identified broad ethical issues not yet on the agenda of EU policy-makers and developers. A separate analysis was conducted for each technology guided by the technology descriptions (Stahl 2011a), consisting of defining features and application areas (Heersmink et al. 2011). The bibliometric analysis was then cross-referenced to ensure all related concepts and issues were considered.⁷ Ranking occurred in a second round of analysis focusing on ethical standards, principles and values identified in EU and national level ethical reviews, advisory reports and policies (Nagenborg & Capurro 2011; Olesky et al. 2011; Szekely et al. 2011), and was performed by all project partners. The second round used legal, gender, ethical and Technology Assessment perspectives in evaluating the technology descriptions as well as the results of the initial ethical analysis, which was based on the literature review, bibliometric and

⁷ Defining features and applications were constructed in Work Package 1, and are available for review on the ETICA web-site (<http://www.etica-project.eu/>).

technology description analyses (Heersmink et al. 2011). Ranking was necessary to ensure issues of immediate or severe importance to policy-makers were highlighted. Common issues, principles and concepts were identified across the range of technologies. The second round of analysis was also supplemented by focus groups including members of the public who were asked to express their concerns relating to AMI (Heersmink et al. 2011).

A weakness of the methodology employed in ETICA as related to the research described in this thesis is its broad scope, focusing on emerging ICT as opposed to PHM, or even medical ICT. Issues were primarily identified through bibliometric analysis of academic discourse concerning ICT ethics. Potential uses of AMI were not limited to healthcare, raising questions over the likelihood and potential importance of the identified issues for PHM, despite the general themes (e.g. autonomy, privacy, surveillance) being mirrored in the PHM-Ethics analysis (see: Section 1.2.4). The analysis does not claim to be exhaustive, instead providing an overview of potential issues at a technology-level. The meaning given to concepts such as privacy and surveillance by stakeholders in specific contexts is not explored, suggesting a need for ‘patient-oriented’ analyses in which the meaning of such broad ethical concepts to particular stakeholders in particular contexts can be understood. For emerging technologies this type of analysis can help explain the expectations and needs of potential users, and perhaps influence development and governance. Without such analysis, responding to ethical problems at ‘ground-level’, or creating solutions around the needs and expectations of specific stakeholders, cannot be accomplished.

1.2.4 Results: Initial Ethical Issues of PHM

The analyses conducted by the projects concluded that the potential ethical implications of PHM and emerging ICTs are mostly extensions of pre-existing ethical issues, principles and concepts, as opposed to genuinely new contributions (Goujon & Flick 2011; Heersmink et al. 2011; PHM Ethics Consortium 2011a); however, the need for extensions or other revisions to pre-existing concepts and principles was noted (Heersmink et al. 2011; Stahl 2011a). Although ETICA studied eleven technologies in total, overlap was found between its analysis of AMI and PHM-Ethics’ analysis of PHM. In ETICA, privacy, surveillance, data protection, autonomy, freedom, equity and liability were seen as important ethical concepts in understanding the implications of AMI (Heersmink et al. 2011), and by extension PHM. Each of these topics was reflected in PHM-Ethics (PHM Ethics Consortium 2011a). The constrained focus of PHM-Ethics reinforces the validity of the conclusions of ETICA about AMI.

Collection, storage, transfer and fair use of data took central importance in both projects. Contextual monitoring of health and daily behaviours made possible through both technologies is a major problem for the privacy of users (Heersmink et al. 2011). PHM was compared to a modern 'panopticon' (Albrechtslund 2005; Light 2010) due to its 'long memory' and influence on the behaviour of users (PHM Ethics Consortium 2011a). Unforeseen combinations of PHM applications can create opportunities for monitoring parameters beyond health, in which the combination of monitoring data about multiple parameters monitored individually provides insight into daily behaviours and the user's private life (PHM Ethics Consortium 2010a). This extension of PHM systems to new users and unintended uses is referred to as 'usage creep' (Lymberis 2003; PHM Ethics Consortium 2010a, p.20). At its most extreme, usage creep could lead to biometric profiling through the linkage of biometric data with PHM and AMI systems, enabling tracking of individuals (Haggerty & Ericson 2000; Heersmink et al. 2011). These imagined scenarios involve infringement of expectations of privacy, and further erode the utility of protection mechanisms such as informed consent, which rest upon the adequacy of knowledge about risks and benefits.

PHM and AMI may also have implications for user autonomy, defined here as "the ability to construct one's goals and values, and to have the freedom to make one's decisions and perform actions based on these decisions" (Brey 2005, p.94). Trust in 'systems' is considered a crucial element in avoiding perceptions of surveillance in PHM, justified or not (Yuan et al. 2007; PHM Ethics Consortium 2010a; Heersmink et al. 2011; Ziefle et al. 2011). The possibility of infringing autonomy increases as emerging technologies are used to replace or assist humans in activities, a problem recognised in ETICA's analyses of Robotics and AMI (Heersmink et al. 2011). Diffusion of applications which supplement human workers is enabled by perceived socioeconomic benefits (Heersmink et al. 2011; PHM Ethics Consortium 2011c), such as cost-savings in healthcare.

1.2.5 Recommendations and Outcomes

Critical review of governance revealed two significant limitations of governance of emerging technologies. First, the inherent uncertainty of the future precludes confident identification of the ethical, social and legal implications of emerging technologies (Ahmed & Skogh 2006; Tannert et al. 2007; Stahl 2011b). Proactive ethical assessment of emerging ICT is required to prevent foreseeable ethical problems. While the predictions made in the projects may never come to pass, the position of uncertain proactivity is preferable to merely reacting to ethical

problems as they occur (Stahl 2011a). Researchers, policy-makers and civil society tend to undertake actions meant to shape the future in desirable directions without absolute certainty over its course (Brey 2011; Stahl 2011b); proactive ethical assessment should be seen in this light. In designing this research project, the need to continue this future-oriented, proactive discourse is recognised, as well as the difficulties faced in such approaches to ethics (see: Chapter 7).

Second, in so far as people live in specific contexts and not the abstract, ethical issues occur in specific contexts and are experienced by specific stakeholders. Ethical analysis is intended to influence real contexts and affect the lives of real stakeholders, suggesting that ethics is not a single-event preceding development or deployment of an ICT. This is not to suggest that abstract theories and principles have no place in ethics, but rather when the aim of ethical analysis is 'applied' in the sense that it seeks to influence the actions and outcomes of individuals in real contexts, characteristics of the context and stakeholders involved must be considered. Both projects share a concern with the lack of context-sensitivity in governance approaches. Much of the literature reviewed in PHM-Ethics focused solely on implications for social systems rather than users (PHM Ethics Consortium 2011b). This situation is problematic because stakeholders in different contexts experience issues differently according to varied expectations, moral values, principles and beliefs.

Norms are prescriptive statements given content and relative importance within specific contexts by stakeholders. Many governance schemes treat norms as statements separable from context, amenable to logical deduction (Musschenga 2005; Stahl 2011a), leading to the exclusion of relevant perspectives and emphasis on sectoral and specialist interests in ethics discourses (Stahl 2011a). Approaches which seek to provide general specifications of norms applicable across multiple contexts therefore fail to capture the importance of context in articulating and comprehending norms. In light of this concern, the projects recommend the future assessment of emerging technologies at the application-level, by which implications are unique to specific contexts and fully understood only through the inclusion of stakeholders in development and governance (e.g. Joss & Bellucci 2002). Through civil participation, ethical, social and legal issues of practical importance can be identified and headed off.

In response to the limitations identified in governance, the projects focused on improving governance schemes through the creation of ethical assessment methodologies. In

comparison to PHM-Ethics, ETICA provided broad policy and development oriented recommendations to create an environment in which proactive ethical assessment is possible. ETICA's recommendations are aimed at policy-makers as well as industry, researchers and CSOs, recognising their diverse roles in ICT governance: policy-makers formulate regulatory frameworks which govern ICTs as they emerge, while industry, researchers and CSOs are "innovators and users of ICT...who ought to be proactive in their consideration of ethics" (Stahl 2011a, p.3). In contrast, the recommendations made by PHM-Ethics are, although policy-oriented, focused primarily on the specifics of stakeholder participation in governance and context-sensitive assessment. PHM-Ethics recognised the need for a regulatory framework which encourages "interactive ethical assessment," in which contextual understanding of norms and stakeholder participation are enacted in assessment and development going forward.

1.2.6 Comparison of Aims, Methodologies and Outcomes

The research described in this thesis builds upon PHM-Ethics and ETICA. PHM is conceived of as an emerging technology, meaning the opportunity remains to influence its design, governance and usage, with proactive assessment being preferable to reactive governance. The need to include non-expert stakeholders in assessment, and the associated call for context-specific assessment of PHM, is recognised as necessary to improve understanding of the technology's potential ethical implications. This type of assessment was not carried out in either project, meaning that future assessment of ethical issues outside of governance do not benefit directly from either project (see: Section 1.2.3).

The research described in this thesis differs from PHM-Ethics and ETICA in terms of aims, methodologies and outcomes. PHM-Ethics and ETICA had primarily procedural aims, the outcome of which was the improvement of governance of PHM and emerging ICT through the development of new assessment methodologies. Both projects addressed procedural weaknesses of governance, and sought practical solutions. The research described here is altogether different with conceptual rather than procedural aims, focusing on the theoretical moral potential of PHM as a technology, comprehended through a conceptual framework which can help identify and specify ethical implications of emerging PHM applications specific to future contexts and uses. Such a framework can contain theoretical analysis of the technology through which implications are identified; relevant theories help 'make sense' of the moral potential of PHM by identifying or otherwise explaining potential ethical issues from

a theoretical perspective. This type of theoretical analysis, intended to contribute to future context-specific assessment of individual PHM applications, was not carried out in PHM-Ethics or ETICA. The research described here can thus be seen as filling a gap in PHM ethics discourse not addressed by either of the framing projects.

As an example of how this research builds upon PHM-Ethics and ETICA, the initial list of ethical issues offered by both projects will be expanded by taking a conceptual rather than descriptive approach, or by interpreting extant literature concerning ethical aspects of PHM through different theoretical 'lenses'. This responds to a limitation of the analyses carried out in both projects, which were primarily descriptive and lacking a theoretical framework through which themes in the literature could be identified. Instead, broad themes were identified based on existing ethical concepts and principles, such as privacy, autonomy, and informed consent (Heersmink et al. 2011; PHM Ethics Consortium 2011c), with PHM merely giving rise to new issues described in these terms. This limitation is perhaps unsurprising, as both PHM-Ethics and ETICA sought to create methodologies for the ethical assessment of emerging applications, not to conduct a conceptual analysis of the technology itself.

The outcome of the conceptual approach undertaken here is a conceptual framework which facilitates understanding and resolution of ethical issues arising in practice (for example, in clinical encounters or home-based care), which cannot be solved proactively through governance or participatory design. The process of coming to understand the ethical implications of emerging ICT is as much about revealing the unique moral potential of the technology, as it is about placing the technology into the pre-defined conceptual categories with which existing 'technosocial' interactions are understood. Where existing normative frameworks prove inadequate to clarify the implications of emerging ICT, conceptual innovation is required (cf. Borry et al. 2008; Kon 2009). It is hoped that future discourses between stakeholders, most importantly those occurring outside of governance schemes, will be enhanced by the conceptual framework which clarifies the moral potential of PHM to 'cause' ethical issues in future contexts. Such a framework is necessary because ethical assessment of emerging technologies is limited to tools, concepts and theories from prior discourses of other technologies, which cannot address the transformational or unprecedented effects of the new technology. The framework may help stakeholders understand the ethical implications of using PHM, or to locate their particular moral values in

relation to the technology, or simply to increase awareness of the potential for PHM to have undesirable implications beyond claimed benefits (e.g. Nordgren 2012).

1.3 Research Questions

Before any theoretical analysis of the literature and non-expert stakeholders can be undertaken, a clear definition of PHM is necessary to demarcate the technological applications under study. This need leads to the project's first research question:

How can PHM be defined?

The first step of the research then must be a review of PHM applications to define the technology. The construction of the conceptual framework would benefit from linking technological features of these applications to specific ethical implications, so as to clarify which implications are initially relevant to which types of applications and users (e.g. patient and demographic groups). This need leads to the project's second research question:

How can PHM be categorised to link potential ethical implications to specific emerging applications?

Addressing these questions, the next chapter builds a definition and categorisation of PHM based upon a review of the PHM-Ethics Taxonomy as well as academic literature discussing ethical aspects of PHM.

These questions do not exhaust the research scope of the project. In Chapter 3 an additional research question is defined in response to perceived gaps in PHM ethics discourse reflected in extant literature, which further narrows the scope of the ethical implications considered in this project. Later, in Chapter 5, a fourth research question is identified in response to the need for an empirical methodology capable of ethically assessing the views of potential users of PHM, understood as an emerging technology.

1.4 Structure of the Thesis

Before moving on to definitions of PHM, it is worth reviewing the structure of the thesis. The thesis can be divided into two halves. Chapters 1 through 5 address substantive issues with PHM, describing the current state of PHM ethics discourse and suggesting ways to move it forward through conceptual innovation and empirical research. The first two research questions are addressed in Chapter 2, which defines PHM and categorises it according to

ethically relevant features as identified in academic discourse. Chapter 3 then critically reviews the same literature, focusing on the ethical implications of PHM, identifying weaknesses and linkages between the various themes seen in the discourse. On the basis of these chapters a gap in the discourse is identified relating to the implications of PHM as a mediator in medical relationships, which can be 'made sense of' through Habermas' notion of 'colonisation of the lifeworld'. This gap helps define the project's third research question concerning the ethical implications of PHM for medical relationships.

To begin to address this question, Chapter 4 describes a novel conceptual framework built from multiple sociological and ethical theories for analysis of the ethical implications of PHM for medical relationships and practice. To assess its limitations and explanatory power, a need is identified to apply the conceptual framework to a particular context into which PHM is predicted to be deployed in the near future. As the final chapter of the first half of the thesis, Chapter 5 describes England as a context for empirically studying the implications of introducing PHM into the world's largest national healthcare system.

The second half of the thesis describes methodological and epistemic issues with studying PHM and emerging ICT in general, before presenting results of the empirical study called for in Chapter 5. Studying PHM through the views of potential users necessitates an empirical methodology which accounts for the epistemic restrictions of research under conditions of uncertainty. Chapter 6 begins to describe such a methodology, including an overview of philosophical paradigms to ground the study and criteria for assessing its quality. Chapter 7 expands the methodological foundation laid in Chapter 6 with an explanation of the epistemic difficulties of research under uncertainty. An approach is described which is capable of joining empirical data with ethical analysis under conditions of uncertainty, relying upon an extension of Habermasian thought to explain the epistemic difficulties of studying the future.

Turning to the conduct and content of the empirical study, Chapter 8 provides practical details about how the empirical study was carried out. Chapter 9 then describes a method of data analysis consistent with the methodological and epistemic decisions taken in Chapters 6 and 7, before presenting the results of the empirical study with attention given to links with the themes identified in Chapter 3. Results are linked to the conceptual framework described in Chapter 4, demonstrating its explanatory power and limitations. Chapter 10 then concludes the thesis, reviewing how each research question was addressed and summarising

recommendations made throughout the thesis. Finally, limitations of the project and areas necessitating further research on the basis of the preceding analysis are identified.

1.5 Conclusion

The primary contribution of the thesis is a conceptual framework built upon empirical and theoretical analysis of PHM as an emerging technological mediator in human and professional interactions. The framework is intended as a tool to improve the dialogue between stakeholders in medical relationships by identifying potential effects of PHM within specific contexts of use, so as to create a fairer discourse in which the implications of the technology are clearer to all stakeholders. Before the framework can be constructed, the state of PHM ethics discourse reflecting current knowledge of the technological scope of PHM and its ethical implications must be reviewed.

2 Chapter 2: Defining PHM

2.1 Introduction

To start building the conceptual framework called for in the previous chapter, it would be helpful to categorise PHM to link potential ethical implications to specific applications, so that it can be said applications of type A potentially (or are more likely to) cause issues X, Y and Z. In this chapter categories are created based on a review of current academic discourse regarding the ethical implications of PHM. By definition an ethical implication of a technology is based upon some characteristic of the technology or application. Categorisation is an attempt to identify and group applications according to these underlying characteristics implicit in predicted ethical implications of PHM; for example, systems which collect vocational data have the potential to cause privacy concerns over tracking behaviours unrelated to health.

Before categorisation is possible, a clear definition of PHM is required to identify relevant systems. Initial exploration of PHM ethics literature and analysis of the results of PHM-Ethics (PHM Ethics Consortium 2012; Schmidt & Rienhoff 2013) revealed that a common definition of PHM does not exist. The term itself is rarely used, with synonymous and related phrases preferred including “telehealth and telecare” (Kaplan & Litewka 2008), “assistive technologies” (Demiris & Hensel 2009; Tiwari et al. 2010), “ambient intelligence and ubiquitous computing” (Bohn et al. 2005; Kosta et al. 2010), “somatic surveillance” (Monahan & Wall 2007), “wearable health sensors” (Lymberis 2005; Arnrich et al. 2010) and “surveillance technologies” (Niemeijer et al. 2010). The terminology reflects the breadth of emerging applications which may be considered PHM.

In response to the research questions posed in Chapter 1, a systematic review of PHM ethics literature is undertaken in this chapter for three reasons: (1) to provide an overview of applications fitting the definition of PHM; (2) to identify any further restrictions on this definition necessary to distinguish PHM from other medical technologies; and (3) to categorise PHM technologies linking potential ethical implications to specific applications. Any answer to these questions must be preliminary; as new systems are developed, the categorisation requires updating in recognition of emerging ethically relevant features (PHM Ethics Consortium 2011b).

2.2 Defining PHM

A definition of PHM based upon an extensive literature review was created in the PHM-Ethics project, where PHM is defined as “all technical systems collecting, processing, and storing data linked to a person. It allows monitoring parameters of that person and can lead to health-related information of that person” (PHM Ethics Consortium 2011b, p.6). PHM has a diverse range of application areas within healthcare, including prevention, treatment, assistance and rehabilitation, as well as occupational and recreational health monitoring. Within these areas PHM applications are used for a variety of purposes including longitudinal data monitoring, early diagnosis, detection of anomalies and emergencies and lifestyle feedback (PHM Ethics Consortium 2012).

The PHM-Ethics definition is purposefully broad to allow for the inclusion of future technological developments (Gök et al. 2013, p.68). Although a large variety of systems may be considered PHM, the PHM-Ethics definition is excessively broad. Many established as well as emerging medical systems fit the definition, from in-hospital heart and ECG monitors which automatically alert staff to emergencies to smart home systems which monitor the health and related behaviour (e.g. sleep patterns) of dementia patients. A narrower definition is required to distinguish PHM as an emerging medical ICT, distinct from existing medical ICTs.

On this basis a narrower working definition was created for a systematic review of the literature, intended to ensure that all sources discuss systems with sufficient similarity. For the review, PHM was defined as **any electronic device or system that monitors and records data about a health-related aspect of a person’s life outside a hospital setting**. To qualify as PHM a system must be capable of transferring data to a third party, and be usable by a layperson outside a traditional medical environment such as a hospital. These additional restrictions to the definition are necessary to bring it in line with the types of systems identified in PHM-Ethics (PHM Ethics Consortium 2011c; Gök et al. 2013). The limitations demarcate PHM from existing monitoring systems by emphasising that PHM (1) occurs in spaces traditionally not subject to medical monitoring and (2) can share data about the patient’s health with others.

These restrictions may not sufficiently distinguish PHM from other technologies in such a way that one can coherently speak of ethical implications unique to PHM as a group of similar medical ICT applications. Recognising this, the definition may require further refinement on the basis of the literature review.

2.3 Systematic Literature Review: Definition and Categorisation

A systematic review of academic literature discussing ethical implications of PHM was carried out. In this chapter the literature is analysed with a view towards defining and categorising PHM, while the next chapter critically analyses the discussion of ethical issues of PHM. While each chapter highlights different aspects of the literature, they address the same sources.

The literature search was designed to systematically identify academic literature discussing ethical implications of PHM, with a search query constructed to move beyond the technological and demographic scope of prior reviews of related technologies (e.g. Niemeijer et al. 2010; Zwijsen et al. 2011). PHM applications often share technical capabilities with AMI and ubiquitous computing (Bohn et al. 2005). The search query was designed to include only health applications, although it is recognised that ethical issues of non-medical applications of these technologies may be relevant to PHM.⁸

2.3.1 Method

Academic literature available in four databases (Scopus, IEEE, MEDLINE, and ISI Web of Knowledge) addressing the ethical implications of PHM was reviewed between May 2010 and September 2012. Attention was given to the discussion of normative issues in each article, with the goal of identifying themes in the literature. The databases were searched to identify literature discussing issues of ethics, privacy or risk relating to the development and deployment of PHM. The search was of all English language sources in the indexed literature. Although most of the reviewed literature consists of peer-reviewed journal articles, other types of publications including commentaries, reviews, books and conference proceedings were included where indexed by the chosen databases. Sources were also identified through citations in literature returned in the database searches.

⁸ For a discussion of ethical aspects of AMI and ubiquitous computing, See: (Bohn et al. 2005; Brey 2005).

2.3.1.1 Procedure

Sources were located through systematic searching of databases as well as through the references of reviewed literature. Multiple search techniques were used to ensure comprehensiveness. Recognising that “Personal Health Monitoring” is an emerging term not yet widely used in the literature, synonyms were used such as “somatic surveillance,” “wearable body sensors,” “personalised health,” “pervasive health,” “assistive technologies,” “ambient intelligence,” “health surveillance,” “ambient assisted living,” “telecare,” “telehealth,” and “smart homes.” All articles matching the synonymous terminology were checked to ensure the technology under discussion matched the working definition of PHM.

The search query consisted of three categories of terms connected via Boolean operators (see: Table 2.1). Recognising that ethical issues are not always identified as such, additional terms (privacy and risk) describing ethical aspects of PHM were included.⁹ The desired outcome of the search query was to identify articles mentioning PHM or related terms that also directly discussed ethics or ethical issues.

Category 1	Operator	Category 2	Operator	Category 3
‘personal* health* monitor*’ and synonyms	OR	‘ubiquitous computing’, ‘ambient*’, ‘surveillance tech*’, ‘assistive tech*’ AND ‘medic*’, ‘health*’	AND	‘ethic*’ OR ‘privacy*’ OR ‘risk*’

Table 2.1 - Search Query

Articles were reviewed to identify discussion of ethical aspects of PHM, and were excluded if they only discussed development, implementation or technical specifications. Requirements were not set for type of article, length or thoroughness of the discussion of ethical issues.

A potential weakness of the search procedure is its focus on ethical discourses. As the search query was designed to identify sources discussing ethical issues of PHM, and not merely PHM itself, the sources returned may provide an unrepresentative sample of PHM systems biased toward those with which authors are particularly concerned with ethical issues. In turn, any

⁹ This decision was made on the basis of feedback from an early version of the literature review presented at ETHICOMP 2011 (see: Mittelstadt et al. 2011)). The review was criticised for limiting the search terminology in category three to the term “ethic*,” thus ignoring issues described purely in terms of privacy or risk. On this basis, ‘privacy’ and ‘risk’ were added to the search string. Privacy was chosen because of its frequency of appearance in the early literature review. Risk was chosen on the belief that normative dimensions of PHM may be termed ‘risks’, and analysed in ‘risk assessments’.

definition or categorisation created based on this range of systems may be similarly unrepresentative of PHM.

To address this potential flaw, examples of PHM were also located through hand searching of developer and commissioning web sites as well as news articles. These additional sources were only considered for the categorisation and definition of PHM, and are not included in the results of Chapter 3 which concern ethical implications of PHM. Systems identified in ETICA and PHM-Ethics, which did not limit their reviews to ethics discourses (see: Section 1.2), were also included. These secondary search techniques provided a more representative sample of PHM systems for categorisation and definition.

2.3.1.2 Data Analysis

All sources underwent content analysis to identify treatment of ethical implications of PHM. Key terms were identified, interpreted and combined into themes present across multiple articles in a process analogous to grounded theory (Strauss & Corbin 1994). Words and passages were highlighted that appeared to refer to ethical issues or concepts. Highlighted segments were then coded. Similar codes were assigned to themes as discussed below (see: Section 3.2).

2.3.2 Results

A total of 569 articles were identified for review through the systematic and secondary searches, 118 of which met the inclusion criteria of explicitly discussing ethical, privacy or risk implications of PHM. Categories were defined according to the location of sensors, which was interpreted as contributing to distinct ethical implications. On this basis three general categories of PHM were identified in the reviewed literature (n=118): Mobile Monitors (n=38), Environmental Monitors (n=79), and In Vivo Monitors (n=4).¹⁰ A brief discussion of each category follows, with numerous examples intended to provide an overview of the types of PHM applications currently available or in development.

The categories aim to group underlying characteristics of PHM which give rise to ethical concerns. Through the categories, implications are connected to the design of the system

¹⁰ The 'n value' identifies the number of sources discussing PHM systems fitting into each category. Sources could occupy multiple categories, such as when a smart home system employs environmental and wearable sensors. Of the 118 reviewed sources, nine failed to provide enough detail for categorisation. See Appendix 1 Table 1.3 for categorised results.

based on the location of sensors. They are not intended to be exhaustive, but rather the first step in constructing the conceptual framework.

2.3.2.1 Mobile Monitors

Mobile monitors are devices which are worn on the body or carried by the user for the purpose of monitoring health parameters, for instance vital signs, stress, and blood quality (e.g. Stuart et al. 2008; Ojasalo et al. 2010). Such devices may be used both to track the progress of a specific health condition as well as for preventative and lifestyle purposes, such as detecting deviance in health parameters at an early stage (Palm 2011), which may indicate the onset of a medical condition requiring treatment. Contextual information can also be gathered by identifying user location and behaviours, which can be linked to changes in health parameters.

The range of mobile monitors is broad and includes wrist and arm bands (see: Figure 2.1), 'smart' clothes (see: Figure 2.2), body area networks (Lim et al. 2010; Mana et al. 2011), global positioning system (GPS) trackers (Landau and Werner, 2010) and smart phone devices (Ganti et al. 2010; Boulos et al. 2011). GPS trackers designed for use with dementia patients and other persons prone to dangerous wandering are already in use (Abbas et al. 2011). Wireless medical sensor networks consist of wearable devices with multiple interlinked wireless sensors (Milenkovic et al. 2006) capable of physiological monitoring, on-site analysis and automatic alerts when factors fall outside normal parameters (Gao et al. 2008; Giannetsos et al. 2011, p.1298). Monitored parameters include blood oxygen, heart rate and ECG (Gao et al. 2008), plethysmographic signal (organ volume changes) (Giannetsos et al. 2011, p.1298) and blood pressure (Laurance 2011). New software can turn existing devices

Figure 2.1 - Blood Pressure Wrist Watch

A patient with hypertension can use a wrist watch style device which monitors their blood pressure (BP) continuously (Laurance 2011). The monitor creates a log of blood pressure fluctuations throughout the day, and can alert the user to an out of range BP. The data can be analysed alongside a log of the user's behaviour throughout the day, which may reveal the effects of the wearer's daily activities. This information may be used by medical professionals to create a personalised treatment or lifestyle plan for the user.

Figure 2.2 - Smart Clothes

Clothes with sensors woven into fabric can measure heart rate, respiration, body temperature and other physiological parameters. Such devices could aid athletes in training and physical competition, or provide early detection of heart conditions for COPD patients (Ure et al. 2012). Emergencies and physical limits could be detected with precision.

into PHM, as shown with health monitoring smart phone ‘apps’ which can track exercise or movement and share data with health professionals and third parties (Pentland 2009; Boulos et al. 2011). ‘Body area networks’, or sensors worn by the user woven into or textiles worn beneath clothing, can be combined with smart phone applications to provide longitudinal health tracking (Lim et al. 2010; Boulos et al. 2011) on devices already familiar to users.

One type of PHM rarely discussed in the reviewed literature with potential implications beyond elderly and chronically ill users are lifestyle monitors, sometimes called “persuasive technology” (Ijsselstein et al. 2006, p.1), which are designed to influence decisions in real-time by providing the user with information about lifestyle behaviours and choices (Berdichevsky & Neuenschwander 1999), suggesting unique implications for user autonomy. Examples include ‘virtual fitness coaches’ and social network visualisations which provide qualitative feedback about the effect of social interactions on mental health and emotions (Jea et al. 2008; Pentland 2009); while these devices do not monitor physiological parameters, they can provide contextual information which may be helpful in interpreting such measurements. Furthermore, lifestyle monitors can provide persuasive feedback to users intended to alter behaviour or promote values and goals seen as desirable by system developers. Ethical principles may be required to ensure such technological persuasion is ethically acceptable (e.g. Berdichevsky & Neuenschwander 1999).

The capacity to monitor location and behaviours beyond established ‘monitored spaces’ suggests mobile PHM may have unique implications in relation to privacy, such as an inability to retreat to non-monitored ‘private’ spaces. Contextual information about non-health aspects of the user’s life may be inferred by tracking location over time, suggesting implications for the user’s ability to control what monitoring data reveals about his life and behaviours. Wearable monitors may also pose a risk of stigma or embarrassment as a visible reminder of the user’s need for monitoring, with potential implications for how the user views himself and interacts with others.

2.3.2.2 Environmental Monitors

Environmental monitors provide information about a patient's private space, such as the home, car or workplace. They do not require the patient to wear, carry or implant sensing devices, but instead use sensors embedded into an environment, although combinations of wearable and environmental sensors are foreseeable. Applications of environmental monitors include smart homes¹¹ (see: Figure 2.3) and related 'gerontechnologies' (Chan et al. 2009), which seek to provide a "cost effective remote healthcare solution in the wake of a growing elderly population and rising healthcare costs" (Stuart et al. 2008). Devices in this category may also be referred

Figure 2.3 - Smart Homes

Chronically ill and elderly persons, confined to their homes, can make use of smart home technologies, which can detect behaviour and health parameters through sensors installed in the home (Frisardi and Imbimbo 2011). Sensors could detect sleep patterns, activity levels, falls, and emergencies and automatically alert family members or medical professionals when an emergency occurs, or a problematic health or behaviour pattern emerges. The effect of medications could also be tracked through behavioural data. Information gathered by smart home sensors could be used to evaluate the care needs of 'at-risk' patients, and keep a 'watchful eye' on them when human carers are unavailable.

to as AMI and ubiquitous computing (ubiquomp) health applications, which typically involve embedding sensors into public as well as private spaces (Brey 2005). Examples include fall detectors, 'smart' beds with weight and movement sensors, 'smart' pillboxes which track and transmit medication dispensing (PHM Ethics Consortium 2011b), motion trackers and pressure sensors which can detect gait (Caine et al. 2006).

In terms of ethical implications, environmental monitors provide spatial information, or how a user moves through and interacts with a space. Spatial awareness enables behaviour tracking, and can provide contextual information related to the user's health condition (Liampotis et al. 2009). Environmental monitors may prove harder to 'escape' in terms of psychological and physical obtrusiveness (see: Section 3.2.4) than mobile monitors which are easily hidden or taken off, assuming sensors must be installed into the user's environment prior to use. Relationships with other members of a household or friends and family may also be affected, based on changes to the 'character' of the monitored space (Roush & Cox 2000) or a perception of being watched (Welsh et al. 2003; Percival & Hanson 2006; Bentwich 2012).

¹¹ An extensive review of smart home systems in development is available in Chan et al. 2008.

2.3.2.3 *In Vivo Monitors*

In vivo monitors require implantation in the user to provide real-time monitoring of

physiological parameters, such as blood chemistry and pressure. Examples include in vivo glucose monitoring chips built on radio-frequency identification (RFID) technology (PositiveID 2011) which may eventually be coupled with in vivo insulin dispenser systems, or an implantable stent monitoring the constitution of blood (Gaul & Ziefle 2009; Pousaz 2013) for chemotherapy or early detection of heart attacks (see: Figure 2.4).

Development of such systems appears

relatively limited compared to other types of PHM (n=4), perhaps because of the ethical issues posed with implanting a technological system into the human body or the ramifications of false positives and negatives. This situation may be a result of the recognition of ethical issues related to implanting ICT into the human body, which introduces issues of human enhancement into PHM discourse (e.g. McGee & Maguire, Gerald Q. 2007; Monahan & Fisher 2010; Coeckelbergh 2011), raising questions related to bodily integrity, justice, and the ethical difference between technologies of 'enhancement' and 'restoration'.¹²

Figure 2.4 - In Vivo Blood Monitoring

Patients with a wide variety of disorders detectable through blood tests could make use of an in-vivo system which monitors the constitution of blood in real time. Possible uses include real-time blood glucose monitoring for diabetics, or early warning of heart attacks from the presence of indicator enzymes which appear in the blood immediately before an incident (Pousaz 2013). The effect of medications could also be tracked in real-time, leading to more personalised health interventions.

2.3.2.4 *Related Technologies*

Overlap exists between PHM and similar technologies including health applications of AMI, ubiquitous computing, assistive technologies (AT), telehealth and telecare (see: Figure 2.5). It is worth reviewing this overlap in terminology to demarcate the applicability of related discourses to PHM.

¹² Although relevant to the discourse, the ethical implications of PHM as a form of human enhancement are not discussed further here due to the relatively limited development of in vivo monitors. In vivo monitors are not ignored from this point forward; however, the unique issues resulting from their implantation within the human body, conceived of as a form of human enhancement, are ignored. The implications of PHM as human enhancement may require further attention if feasibility of in vivo monitors progresses, at which point existing discourses around human computer interfaces may be relevant. For example, see: Hochheiser & Lazar 2007.

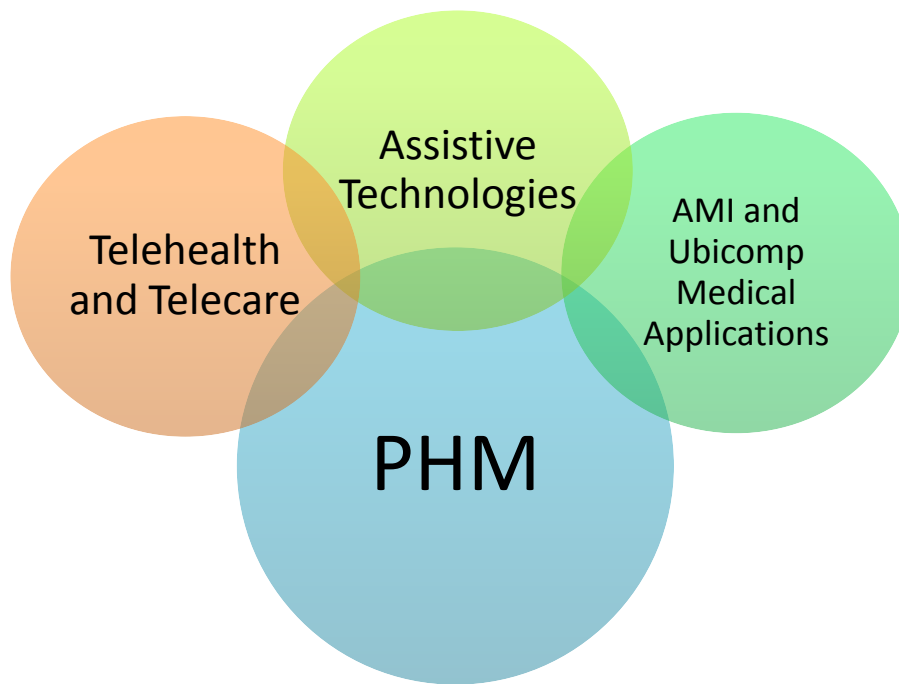


Figure 2.5 - Overlap of Terminology with Technologies Related to PHM

PHM is related to ambient intelligence and ubiquitous computing in the sense that all three aim to monitor the activities of individuals, sometimes including health parameters. However, ubicomp and AMI are terms used to describe a broader range of technologies than PHM, with potential uses in public spaces and for monitoring beyond health parameters (Bohn et al. 2005; Friedewald et al. 2007; Giannetsos et al. 2011). As described here PHM is used to monitor the health of a specific individual or group, rather than the activity of the general public in a particular space. This distinction means that ‘user identity’ is an important concept to distinguish PHM from related technologies; only monitoring technologies in which the identity of the user is known, either to the system or its operators, can count as PHM. Without knowing the identity of the user longitudinal tracking of health and behaviour, as well as feedback based on such data, are not possible. While PHM can be distinguished from AMI and ubicomp in this way, some AMI and ubicomp applications may also qualify as PHM by the definition of PHM offered below (see: Section 2.4)—the technological groupings overlap.

The same is true of assistive technologies, which are designed to assist elderly or disabled persons with impaired daily tasks such as walking, bathing and communication. AT may also support carers by monitoring the user and alerting the carer in an emergency (Chan et al. 2009). PHM can be distinguished from assistive technologies in terms of assistance; the

former are designed primarily to replace or supplement impaired characteristics of the user, whereas the latter only monitor, collect and analyse data, and perhaps alert third parties to relevant events. AT is often lacks networking capacities, whereas PHM relies on the transmission of data off-site (cf. van Hoof et al. 2007, p.156). A crossover exists between the two: a device may be both PHM and AT, but not necessarily so.

Telehealth delivers healthcare services to chronically ill patients via ICT allowing for remote consultations (Department of Health 2011a, p.4). Users may be taught to use health equipment and take health readings at home (Ure et al. 2012) which can be exchanged with their clinician during consultation. Telecare is a subset of telehealth aimed at supporting and monitoring elderly and chronically ill individuals at home (Department of Health 2011a), especially those at greater risk of emergencies or requiring in-home care or support (Stowe & Harding 2010). Telecare typically monitors for emergencies automatically outside of remote consultations (Department of Health 2011a, p.4), and may support informal carers as well (Palm 2011). Telehealth and telecare rely upon networked ICT to interact with patients, and often utilise video cameras, microphones, touch screen displays and ‘traditional’ healthcare devices such as blood pressure cuffs.

PHM is distinct in the sense that users are typically required to input data, answer questions or take measurements with telehealth and telecare (e.g. Ure et al. 2012), whereas PHM can ‘passively’ monitor the user without active measurements such that remote consultations are unnecessary—the patient is instead continuously remotely monitored as opposed to individual instances of data collection. The distinction is, however, controversial—telehealth and telecare systems can utilise PHM type sensors which passively monitor the user (e.g. Stowe & Harding 2010), suggesting that as ‘always-on’ or passive sensing is increasingly built into telehealth devices, the distinction between the three terms will blur further. However, the distinctions should be maintained as PHM has applications outside of the care environments for which telecare is designed, such as preventative health and lifestyle monitoring (see: Section 2.3.2.1).

2.3.3 Discussion

PHM may be categorised and differentiated from related technologies according to sensor location, field of application and technological characteristics. Different ethical implications come with different types of PHM. The categories provide a basis for the discussion of the

ethical themes which emerged from the reviewed literature, by identifying systems for which certain implications are more or less relevant.

Mobile and in vivo monitors enable longitudinal tracking and linking of health and behaviour parameters, which allows for increased interactions between third parties and data representations of the user. Environmental monitors potentially reveal information about private spaces and behaviours, creating a 'public window' into the private lives of users. Spatial information, or how a user moves through and interacts with a space, enables tracking of health-related behaviours in private spaces, such as sleeping patterns and falls. Environmental monitors may prove harder to 'escape' in terms of psychological and physical obtrusiveness than mobile monitors which are easily hidden or taken off, assuming sensors must be installed into the user's environment prior to use. Despite these differences, all types of PHM share certain moral potential on the basis of common technological capacities, such as monitoring and transmitting information about the user's health to third parties.

The categorisation of PHM by location of sensors does not exhaust possible categories linking characteristics of specific applications to potential ethical implications. Additional categories are suggested by the PHM-Ethics taxonomy (Gök et al. 2013), based upon technical features and field of application. Different technical features, such as visual versus non-visual sensing, give rise to different issues (e.g. Caine et al. 2006). Collecting 'simpler' types of data may reduce ethical concerns, for example in comparing monitoring vital signs to daily activity (Gammon et al. 2009). Similarly, different uses of identical systems can give rise to different issues, for example in tracking the location of criminals versus patients with dementia (e.g. Landau and Werner, 2010).

The PHM-Ethics taxonomy (see: Section 1.2.1) contributes to ethical categorisation by constructing different views of the technology based on location, field of application and technical features. By location, systems are categorised according to the location of sensors which can be worn or implanted in the body, or installed in personal or public spaces (Gök et al. 2013, p.71). By field of application, systems are grouped as applications in health care (preventive, treatment related, assistive and rehabilitative), public health, or other health services such as occupational health (Gök et al. 2013, p.72). By technical features, PHM is grouped in a hierarchical tree by a variety of technical features or non-technical features which describe the participants or target groups of monitoring (see: Figure 2.6). The technical view

of PHM consists of a hierarchy in which ethical, psycho-social and legal implications are inherited along branches of the hierarchy based on shared characteristics (Gök et al. 2013, p.73).

The technical hierarchy provides an overview of the range of applications and uses of PHM. The hierarchy incorporates the field of application and sensor location views as well, providing a practical tool for 'mapping' implications of emerging PHM applications against similar existing applications for which implications have already been identified. Each branch of the technical hierarchy need not be reviewed in detail to understand the contribution of the taxonomy to the conceptual framework. The hierarchy shows how emerging applications can be grouped according to technical and non-technical features, with implications inherited along branches of the hierarchy. Increasingly complex systems can be mapped on the hierarchy, and implications traced along the various branches (e.g. PHM Ethics Consortium 2010b, pp.20–1). As a result, the conceptual framework can refer to groups in the hierarchy when identifying implications, rather than individual PHM applications. The taxonomy therefore facilitates applying the framework to emerging applications by establishing a hierarchy of characteristics against which new applications can be mapped.

The conceptual framework bolsters the hierarchy by allowing for implications to be linked across the hierarchy to technological capacities, such as behaviour tracking or lifestyle feedback, or to patient cohorts requiring certain types of monitoring. Importantly, the implications identified in the framework are qualitatively different than those identified in PHM-Ethics; the former will be defined with the help of a theoretical framework and describe implications from the perspective of patients and other non-expert stakeholders, whereas the implications mapped onto the hierarchy in PHM-Ethics concerned governance. The hierarchy and conceptual framework may therefore prove complementary in analysing emerging PHM applications within specific contexts of use beyond governance schemes.

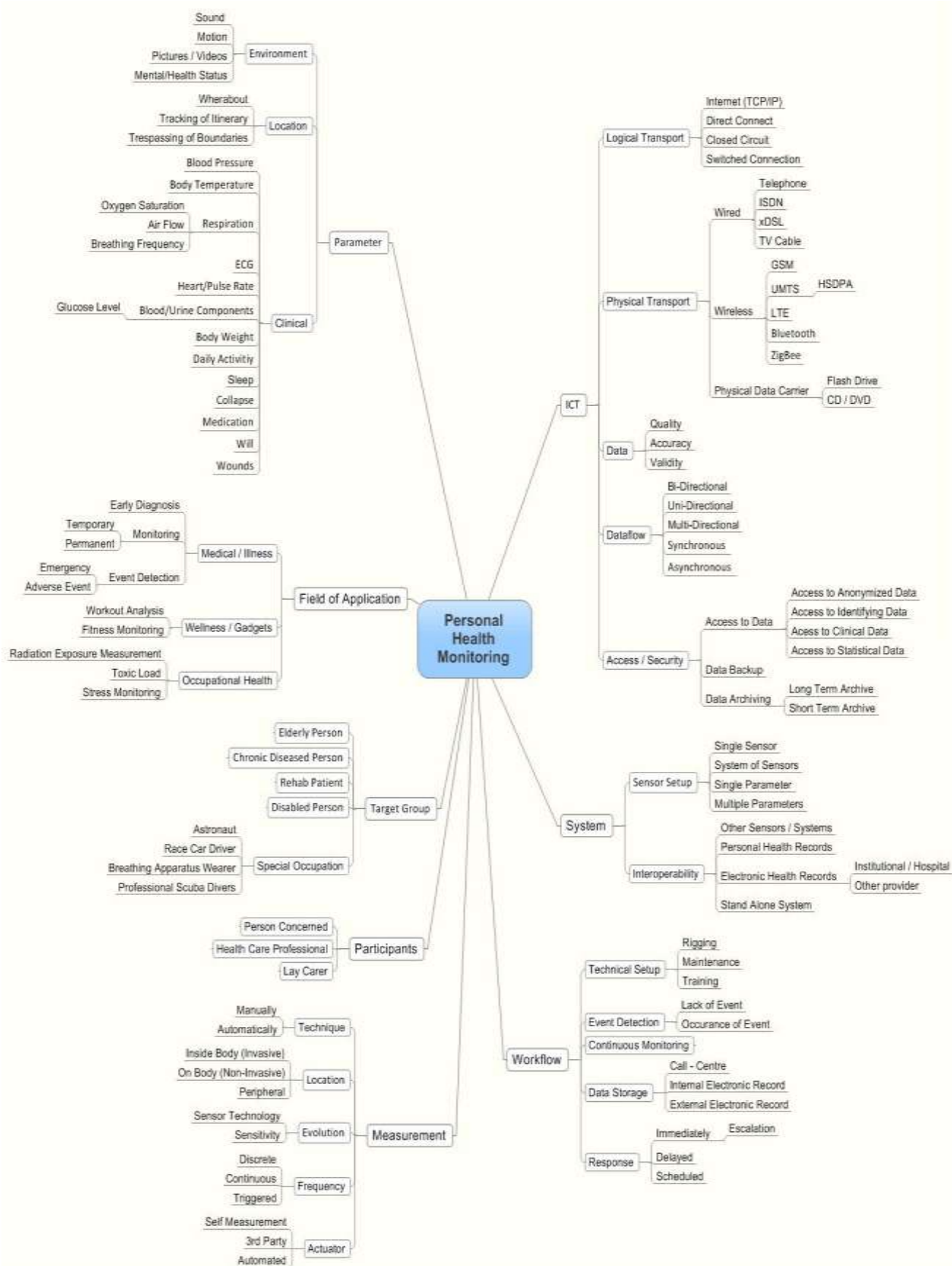


Figure 2.6 - PHM-Ethics Taxonomy: Technical Hierarchy of PHM (PHM Ethics Consortium 2010b, p.18)

2.4 Re-Defining PHM

The review revealed shortcomings in the working definition of PHM based upon comparisons with existing and related technologies. PHM is therefore re-defined in this project as:

Any electronic device or system with the capability to collect, store and transmit data about a health-related aspect of an identified user's life outside a hospital or similar medical environment.

The concept of user identity has been added to show that PHM is distinct from AMI and ubiquitous computing in the sense that the identity of the monitored individual is known in PHM, but not necessarily so for AMI which may monitor public spaces. The capability to transmit data has been added to distinguish PHM from existing consumer health monitors, such as blood glucose or blood pressure monitors which record data but cannot transmit it to a third party. The transmission of sensitive data to third parties gives rise to a range of ethical issues and enhances the importance of user protections, for example privacy and system security. Including it in the definition is necessary to ensure these types of issues are given sufficient attention in PHM ethics discourse, and to emphasise the opportunities opened by PHM to deliver medical care remotely.

2.5 Conclusion

Through reviewing current academic discourse PHM has been re-defined to better distinguish emerging PHM applications from existing and emerging related technologies. The purpose of defining PHM through review of academic discourse was to clearly demarcate a set of technological applications for which common potential ethical implications can be identified. On this basis PHM was categorised according to the location of sensors, field of application and technical features. Categorisation is intended to facilitate matching ethical implications with emerging PHM applications in future contexts of use.

With a definition and categorisation of PHM established, it remains to be seen what types of ethical implications can be matched with different PHM applications. As a first step in this direction, a review of academic discourses concerning the ethics of PHM can help identify an initial set of ethical implications. In the following chapter the literature discussed here is revisited to identify themes in the treatment of ethical implications of PHM, as well as gaps in the discourse related to the implications for stakeholders, beyond problems with governance schemes identified by prior research (see: Section 1.2).

3 Chapter 3: Review of Ethical Implications

3.1 Systematic Literature Review: Ethical Implications

A systematic literature review of academic literature discussing ethics and PHM was carried out to critically assess academic discourse of ethical implications of PHM. The method of the review was described above (see: Section 2.3.1). This chapter presents the results of the review relating to the treatment of ethical implications of PHM. Gaps in the discourse are identified, focusing on implications for stakeholders, *beyond* governance, which require further research. This focus acknowledges the results of PHM-Ethics and ETICA, which have already reviewed problems with governance schemes (see: Chapter 1).

3.1.1 Defining Ethical Implications

Ethical implications are defined here as the effects or outcomes of PHM which give rise to ethical issues. In turn, ethical issues are situations in which different 'right' and 'wrong' actions have occurred or can be taken. Value systems inform conceptions of right and wrong, meaning ethical issues are often problematic situations characterised by conflict over the correct course of action. The justification for defining a situation as problematic varies by different ethical theories, but typically involves benefiting or harming something regarding as 'morally valuable', such as human goods, rights, needs, preferences, and experiences of pleasure or pain (cf. Singer 1993; Kant 1998; Mill 2002; Darwall 2003). The realisation or protection of these goods provides motivation to take action—hence they are valuable. The value of such goods varies by source and intensity according to different ethical theories, but the understanding of goods as something worth protecting or realising grounds ethics as a discipline.

Ethical issues are addressed through the evaluation of actions as more or less right according to different value systems. Ethics consists of the formalised principles or conceptions of the good life that justify differing systems of morality (Leget et al. 2009). These principles can be used to compare and rank the moral values, or criteria for preferring certain actions and outcomes, of diverse groups, as well as to solve disputes, describe the good life or justify actions as right or wrong. It is the dispute between differing value systems or the correct values from which to derive acceptable actions, and the justification for each system's prescriptions, which define something as an ethical issue.

Morality, or moral decision-making, is defined here as the process for resolving ethical issues through deciding on a course of action justified by a particular value system, ethical theory or the relative value of a human good. Moral decision-making is expressed through normative claims, where normativity refers to a variety of norms or reasons supporting an action, including legal norms, moral norms, practical norms, etiquette (Molewijk et al. 2003, p.70), or any other norm meant to justify actions.

The values or norms by which ethical issues are evaluated and addressed come from different theoretical approaches to ethics. According to teleological theories, ethics is the a discipline which helps us understand how to realise our essential nature as humans, or how to achieve the rational happiness unique to humans as a species (MacIntyre 2007, p.52). Another way of conceiving of the discipline is that it aims to provide a philosophical answer to the question “How should one live?” (Habermas 1993, pp.116–7). To answer this question a concept of the ‘good life’, or the “true nature” which humans seek to achieve (e.g. *telos*) is necessary (MacIntyre 2007, p.52). From this approach ethics does not prescribe ‘right’ actions or reasons for acting, but rather defines conditions or traits (e.g. virtues) necessary to lead a good life, the possession of which disposes one to good actions and to realising the human *telos* (MacIntyre 2007, p.53). Without a *telos* humans would lack an initial reason to want to be moral (MacIntyre 2007, p.56), or motivation to choose moral actions. This is not to suggest that an individual is born with certain traits and leads a good life as a result; rather, the individual must reason between possible actions, choosing the one through which the good life is realised. The reasoning in this choice is guided by virtues, and as such the individual is pre-disposed, but not pre-determined, to act ‘good’.

Teleological approaches have been criticised for being morally relativistic by defining virtues against culturally-relative social roles or practices, meaning ‘good’ or morally correct character is defined relative to a particular culture, not universal ideals. Emancipation through appeal to rational moral ideals may be impossible in a teleological view (Habermas 1993, p.125), although this criticism only applies to static or pre-determined conceptions of the good life which does not necessarily apply to modern teleological theories in which *telos* is defined over a life time (e.g. MacIntyre 2007). Alternative conceptions of the distinction between ethics and morality not vulnerable to these criticisms are possible beyond the separation into conceptions of the good life for the former, and rules or principles which guide action to achieve that good life for the latter (cf. Stahl 2008, p.157). Instead, moral practices can be

seen as requiring formal ethical justification which can be provided by a number of ethical theories, such as appeal to Kant's categorical imperatives or Habermas' theory of discourse in which the quality of discourses and validity claims justify moral practices (Stahl 2008, p.151). Justification of actions in this case is not linked to a conception of the good life and *prima facie* principles accepted as leading to it, but rather comes from adherence to imperatives of rationality (Kant 1998) or the validity claims of an ideal discourse (Habermas 1984; Habermas 1985).

A teleological approach is at odds with a Kantian deontological approach (e.g. Kant 1993; Kant 1998; Kant 2003), which requires the individual to take the "moral point of view" in deciding between actions, from which his decision is guided solely by reason. From this view the individual is required to act impartially, choosing 'right' actions over 'good' actions, or those actions "which all could will," evaluated only in terms of autonomy and justice (Habermas 1993, p.118). The Kantian approach considers 'goods', or things which lead to the 'good life', as equivalent to other subjective needs and wants, lacking any status in moral decision-making. The individual therefore makes decisions purely through reason, ignoring the contextual, communal and interpersonal bonds in which the decision occurs, in an attempt to lead an ideal life defined by autonomy and justice (Habermas 1993, pp.119–20). This account of ethical decision-making, or deciding how to act in a particular situation, relies upon 'universal' reasons which by definition ignore the unique characteristics of particular contexts, such as the consequences of the chosen action, in evaluating 'right' actions.

Regardless of the theoretical position taken with regard to an ethical issue, moral relativism, or the state in which all possible actions are seen as equally acceptable in addressing an ethical issue, should be avoided if ethics as a prescriptive discipline is to have a purpose. Relativism is related to emotivism, or the position that moral beliefs are mere expressions of subjective opinion and thus cannot be proven or criticised from a rational basis or proven through argumentation (Edgar 2002, p.46; MacIntyre 2007, pp.23–4). While the theories described here have different approaches to justify actions with ethical conceptions such as the good life, universal principles or validity claims, each implicitly endorses the possibility of distinguishing between right and wrong actions by some criteria, through argumentation. If moral relativism is accepted, we surrender the emancipatory possibility of appeal to 'rational' moral ideals or conceptions of the good, defined for example through virtuous behaviour, as a means to criticise 'wrong' actions. Procedural approaches to ethics, such as Habermas' discourse ethics

(Habermas 1984; Habermas 1985) (see: Section 7.3.2), provide a way out of the relativist trap; while particular positions are possibly subjective, a structured approach to ethical decision-making guarantees that, in establishing norms for cooperative social life, all stakeholders can advance and question claims by identical rational criteria. Even without a procedural approach to ethical decision-making, ethical assessment must be seen as a quest to avoid purely relativistic guides to action through rational argumentation if it is meant to improve the quality of social life against some ideal. The fact that the entities affected by this process have interests (cf. Singer 1993), or can benefit from or be harmed by decisions, further suggests that all claims and outcomes should not be equally valid.

3.2 Results¹³

Academic discourse discussing ethical implications of PHM was reviewed to assess the types of ethical issues, theories and concepts linked to PHM. A total of 118 sources were reviewed. Nine ethical themes were identified across the literature. In addition to the categories of PHM discussed above, five demographic groups of target users were identified during review of the literature. The literature is organised into tables by category in Appendix I.

The following is a thematic overview of the findings. Although the ethical themes emerged according to frequency¹⁴, the overview does not merely highlight this frequency. Rather, the discussed results were chosen for one of four reasons: (1) to draw attention to common interpretations of ethical themes and concepts, (2) to emphasise individual cases and issues that demonstrate ethical implications, (3) to highlight studies with an in-depth analysis of ethical concepts and issues, and (4) to identify gaps in the discussion in need of further research. The discussion focuses on the author's analysis and interpretation of the literature.

Before proceeding with the overview, definitions are required for terms used in discussing the results. The creators or subjects of data (e.g. who the data is 'about') are denoted as 'users'. This title highlights the interaction between persons and PHM systems, which creates the data affecting privacy. The identity of the user is known to the system or its operator, whether real or pseudonymous. Persons or organisations that handle the data once created are referred to as 'data custodians'. Other stakeholders, including carers, clinicians, healthcare professionals

¹³ The results of the literature review concerning themes in PHM ethics discourse have led to the publication of articles in conference proceedings (see: Appendix 17) and one manuscript currently under peer-review for publication in the International Journal of Technoethics (see: Appendix A18.1).

¹⁴ N-values for each ethical theme can be found in Appendix 1 Table 3.

and management may also have a claim to the data. A 'misuse' of data is any use (e.g. searching, analysis, comparison) to which the user has not consented. Data refers to measurements of quantities and qualities which can be interpreted, compared and analysed.

3.2.1 Privacy

Privacy emerged as the dominant theme in the reviewed literature, often being connected to or defined by issues of autonomy, stigma, security and risk. Of the 118 sources reviewed, 68 sources mentioned privacy. Of these, 33 sources addressed designing PHM or underlying security/privacy architectures, 20 were empirical studies into user, family or professional attitudes, 12 reviewed literature about privacy, risk or security aspects, nine were theoretical analyses or conceptual discussions, five analysed normative dimensions of future scenarios of PHM usage and two were risk assessments. Two general types of privacy emerged: data privacy and personal privacy.

3.2.1.1 Data Privacy

A majority of the reviewed literature focused on aspects of controlling and disseminating data about oneself. Data privacy was interpreted as the right to control data about oneself and limit third-party access (e.g. van De Garde-Perik et al. 2006; Tentori et al. 2006; van Hoof et al. 2007; Jea et al. 2008; Mitseva et al. 2008; Chan et al. 2009; Demiris 2009; Tiwari et al. 2010; Mittelstadt et al. 2011). At its narrowest, data privacy was equated with hiding personally identifiable data from unauthorised parties (Ahamed, Talukder & Kameas 2007; Garcia-Morchon et al. 2011), and was seen as quantifiable (Srinivasan et al. 2008). Concerns over data control were common among participants in empirical studies (Melenhorst et al. 2004; Coughlin et al. 2007; Courtney 2008; Little & Briggs 2009; Wilkowska et al. 2010) although qualitative dialogue to understand their motivations was found less often (e.g. Beaudin et al. 2006a; Percival & Hanson 2006; Coughlin et al. 2007; Coughlin et al. 2009; Dorsten et al. 2009; Little & Briggs 2009). Unauthorised access or identification of the user may be prevented through anonymisation at data collection (Agrafioti et al. 2011), with access policies allowing chosen actors access to identifiable data (Bagüés et al. 2007a; Subramaniam et al. 2010; Garcia-Morchon et al. 2011) for acceptable purposes (Beaudin et al. 2006a; Massacci et al. 2009; Chakraborty et al. 2011). Transparency of relationships between data collected and purposes of collection is central to protecting privacy of users (Giannotti & Saygin 2010), who make decisions regarding acceptable uses.

Data privacy empowers users to control the information revealed to others, limiting opportunities for unwanted disturbances and exploitation. Information enables regulation, behavioural control and social categorisation by those with greater access (Kosta et al. 2010), so controlling information flow enhances dignity, autonomy and privacy by acting as a check on the power of data custodians (Friedewald et al. 2007; Moncrieff et al. 2009). Risks associated with uses of personal data beyond those found acceptable by users require “strict guidelines of confidentiality” to prevent unwanted personalised marketing and insurance premiums (Percival & Hanson 2006; Kosta et al. 2010), or discrimination against (non)users wishing to limit access to their personal data (Brey 2005). It would appear that information about temporal limitations and purposes for data use need to be available to users before data gathering to limit data misuses and come closer to an ideal of informed consent, by which the user is able to understand the potential for misuse.

Despite the empowerment derived from data privacy, it appears absolute control over personal data may not be necessary for PHM to be accepted by users. Empirical studies into attitudes towards PHM revealed a preference to forego data privacy in emergency situations (Rashid et al. 2007, p.191; Steele et al. 2009), suggesting a need to find a balance between the desire to control data and enjoy the benefits of services which require that data. A similar balance is expressed in preferences towards PHM for data gathering over human intrusion into the home (Essén 2008). User-end policies have been proposed as a solution which allows users to pre-define a customised level of privacy meeting their expectations (Friedewald et al. 2007; Massacci et al. 2009; Garcia-Morchon et al. 2011).¹⁵ Privacy tools such as these are said to enable users to interact with a range of PHM systems without negotiating individual privacy agreements, while respecting the necessity of informed consent (Bagüés et al. 2007a). Reliance upon ‘enterprise’ level policies, in which data custodians (rather than users) define appropriate uses of stored data, are seen as inappropriate in scenarios in which users are constantly in contact with multiple monitoring systems (Friedewald et al. 2007, p.27; Bagüés et al. 2010, p.342).

Many of the challenges to data privacy stem from the capacity to collect large amounts of data about the personal lives and health of users, which can be organised and searched, enabling

¹⁵ User ownership of personal data has also been suggested as a solution to data mining risks presented by PHM (Pentland 2009); this solution would, however, present a significant barrier to the realisation of legitimate commercial and research interests, and would require sophisticated legislation detailing appropriate third party uses of personal data without the explicit consent of the data owners.

various forms of data mining and profiling (Bohn et al. 2005; Friedewald et al. 2007, p.15). Contextual information is required to understand the meaning and importance of such data, which justifies increasingly pervasive data collection in the name of better service or improved health outcomes. It is this 'feedback loop', in which increasingly pervasive health monitoring justifies further surveillance and classification of users as 'at risk', in which health surveillance concerns seem most plausible.

3.2.1.1.1 Security

Although not included in the search query, security emerged as a theme in data privacy literature. Privacy and security were frequently conceptually interchangeable (e.g. Ahamed, Talukder & Haque 2007; Chan et al. 2008; Stuart et al. 2008; Wang et al. 2008; Armac et al. 2009; Garcia-Morchon et al. 2009; Busnel & Giroux 2010; Dhukaram et al. 2011; Elkhodr et al. 2011; Mana et al. 2011); ensuring system security through appropriate frameworks and encryption algorithms was taken to guarantee user privacy. The concepts can be differentiated by their ends: security is concerned with guaranteeing the *quality* of the data collected by and passing through a system in terms of "confidentiality, integrity and availability" (Giannotti & Saygin 2010, p.75), enabling users to protect privacy by controlling dissemination of personal data. Under this distinction, security mechanisms may alert a user to flows of information between systems and stakeholders (Moncrieff et al. 2009), which could be limited to respect data privacy.

Security risks were defined in terms of interception, modification and falsification of sensor data (Acharya & Kumar 2010; Lim et al. 2010), and authentication schemes (Massacci et al. 2009; Subramaniam et al. 2010; Giannetsos et al. 2011).¹⁶ Security frameworks including key management schemes, encryption algorithms and authentication mechanisms were seen as protecting the confidentiality, integrity and flow of data passing through PHM systems (Chan et al. 2009; Acharya 2010; Fragopoulos et al. 2010; Giannotti & Saygin 2010). Confidentiality refers to limiting access to data to stakeholders with authorisation (Giannotti & Saygin 2010, p.77; Giannetsos et al. 2011, p.1299). In these terms, security features enhance a user's ability to control and trust his data—the conceptual confusion seen in the reviewed literature is therefore unsurprising.

¹⁶ An extensive review of technical security risks is provided by Armac et al. (2009).

3.2.1.1.2 Trust

Trust emerged in the reviewed literature as a necessary component for PHM systems to be seen as 'privacy enhancing' (e.g. Rashid et al. 2007; Yuan et al. 2007; Wang et al. 2008; Coughlin et al. 2009; Bagüés et al. 2010; Chakraborty et al. 2011; Dhukaram et al. 2011), when privacy is interpreted as control over personal data. In the context of data privacy, trust is interpreted as an interaction between a system that collects and processes data, the users that provide the data, and stakeholders who access it.

A lack of trust in a system has been linked to reluctance among potential users to use systems (Brey 2005; McLean 2011). Users 'place trust' in systems and stakeholders to handle their data responsibly, which facilitates and secures data sharing (Little & Briggs 2009; Bagüés et al. 2010, p.352; Kosta et al. 2010). Trust can be interpreted as a sum of the credibility, motivation, transparency and responsibility of a system. Credibility is linked to 'loyalty' or 'reputation' (cf. Rashid et al. 2007, p.190; Little & Briggs 2009); a stakeholder must be seen as responsible or credible enough to handle sensitive personal data. Motivation refers to the intentions of stakeholders, or how they intend to use the data of users. To achieve trust these motivations, as well as the extent of data held, must be transparent to users so that the system (and its custodians) are seen as responsible.

Trust is something that develops over time, based upon development of the system and stakeholders involved (Giannotti & Saygin 2010). Trust exists in stakeholders relationship into which PHM is introduced, for example when replacing 'face-to-face' clinical encounters with 'virtual consultations' (e.g. Chan et al. 2008; Department of Health 2011b).

When trust is breached, for example if an unauthorised third party accesses data, it must be clear who can be held responsible, and to what extent (Little & Briggs 2009). Systems and stakeholders that clearly establish responsibility before a system is implemented are, according to this conception of trust, more trustworthy.

3.2.1.2 Personal Privacy

Personal privacy describes aspects of privacy not related to control of data, although the distinction between data and personal privacy is not always rigid in the literature. By controlling the dissemination of personal data, a person may be spared future physical, social and decisional disturbance from third parties, such as friends, family and service providers (e.g. Friedewald et al. 2007, p.16). Personal privacy was interpreted to mean the right to be left

alone or not monitored by a third party (e.g. Pallapa et al. 2007; Demiris & Hensel 2009; Dorsten et al. 2009; Wilkowska et al. 2010; Mittelstadt et al. 2011), which affects intimacy and control over private spaces (Gaul & Ziefle 2009; Ziefle et al. 2011).¹⁷ Personal privacy can also be a freedom, to “escape being observed or accessed when desired” (Essén 2008, p.130), implying a duty to respect the desire for isolation. The introduction of PHM may cause a gradual loss of personal privacy (Steele et al. 2009), particularly among smart home systems (Coughlin et al. 2007; Demiris 2009; Dorsten et al. 2009). Monitoring technologies can create a psychological disturbance, sometimes called obtrusiveness (Hensel et al. 2006; Nefti et al. 2010), expressed as a feeling of ‘being watched’; certain technologies, particularly cameras, commonly inspire this concern (Demiris et al. 2004; Caine et al. 2006; Stowe & Harding 2010; Tiwari et al. 2010; Leone et al. 2011; Zwijsen et al. 2011).

Personal privacy is a multifaceted concept, defined by interactions between individuals, ICT and the natural world, which includes:

- **Physical Privacy** – Physical accessibility of a person to others, defined by physical borders, such as doors and walls (Brey 2005; Essén 2008; Little & Briggs 2009; Bowes et al. 2011). Can include a right to personal space (Kosta et al. 2010), such as the home.
- **Social Privacy** – Control over social interaction through geographical distance, group membership and location. Connected to physical privacy (Coughlin et al. 2007; Bagüés et al. 2007b; Little & Briggs 2009) and social isolation.
- **Decisional Privacy** – Absence of undesired interference from others in making decisions (Essén 2008; Bowes et al. 2011). Decisional privacy enables the expression of autonomy.

Physical and social privacy are placed at risk by the capacity of PHM to transmit data to third parties (Brey 2005; Friedewald et al. 2007), or move personal data past privacy protecting natural, social, spatial, temporal, ephemeral and transitory borders (cf. Marx 2001). PHM increases the interconnectness of users and stakeholders through data sharing which blurs the boundaries between ‘public’ and ‘private’ spaces and data.

Decisional privacy is placed at risk when monitoring is seen as electronic surveillance.

Awareness of monitoring can affect behaviour (Essén 2008), especially risk taking among seniors (Percival & Hanson 2006; Remmers 2010) which may express a desire to retain

¹⁷ The distinction between personal and data privacy was not always upheld in the reviewed literature, with control over dissemination of personal information occasionally understood as a form of personal privacy (cf. Bagüés et al. 2010).

independence at home, despite safety risks. Monitoring may also lead to 'labelling' of users as 'health impaired' or 'at-risk' (Percival & Hanson 2006; Rigby 2007; McLean 2011), further limiting behavioural freedom (Kosta et al. 2010). Alternatively, the user's home may be increasingly freed from external interference by reducing the need for carer visits; whether this is desirable, particularly among the mentally impaired and physically frail, remains a question of appropriate balances between safety, autonomy and self-determination (Remmers, 2010). The need for 'self-care' can be reduced if PHM sends emergency notifications autonomously (Bowes et al. 2011), which violates decisional privacy through automatic sharing of data in the interests of safety, causing an intrusion of a third party into the user's private space.

3.2.1.2.1 Surveillance

These aspects of personal privacy are placed 'at risk' by technologies which enable the digitisation of the body, private life and spheres (cf. Nissenbaum 2004), including behaviours, decisions and physiological parameters. Warnings of a "Big Brother" future in which electronic surveillance pervades private life have become common (Welsh et al. 2003; Brey 2005; Percival & Hanson 2006; Bowes et al. 2011), but perhaps overly pessimistic and too eager to assign responsibility for 'surveillance' to a vaguely sinister 'other' (Essén 2008; Sorell & Draper 2012), be it a medical institution, service provider or government. These predictions may be overblown, as PHM monitors identified users rather than public spaces (see: Section 2.3.2.4). Despite this, the capacity to transmit sensitive personal data to third parties, and the opportunities for building 'health profiles' of users afforded by this capacity (cf. Brey 2005), suggests that pervasive surveillance may be possible through PHM.

3.2.1.2.2 Rights

Personal privacy implies that humans possess a right to freedom of action, expressed in terms of autonomy, self-determination or independence. This right can be (justifiably) violated through third party inference. For instance, actions which undermine a person's independence, such as the installation of PHM at the request of family members (Rigby 2007), are taken to violate decisional privacy because the user is no longer able to act free of external judgment within a private space. To conceive of this as a 'violation' implies freedom of action is worth protecting. Personal privacy is therefore intrinsically linked with political conceptions of humans as rights possessing entities (Remmers 2010; Zwijsen et al. 2011), and with ethical concepts such as autonomy, independence and self-determination.

3.2.2 Autonomy

Although autonomy was frequently identified as an important ethical consideration, it was rarely defined or supported by reference to background theories of autonomy, personhood or human dignity. Autonomy was interpreted to mean the right to make personal decisions (Fellbaum 2008, p.161; Demiris 2009; Islam et al. 2009, p.2), a right to freedom (Brey 2005) or a right to independence (Remmers 2010; Wilkowska et al. 2010; Ziefle et al. 2011). Autonomy was discussed in terms of freedom and independence in the context of assistive technologies (Robinson et al. 2007; Busnel & Giroux 2010; Remmers 2010; Wilkowska et al. 2010; Zwijsen et al. 2011), smart homes (Brey 2005; Remmers 2010; Townsend et al. 2011) and residential care facilities (Dorsten et al. 2009; Zwijsen et al. 2011). Retaining independence in decision-making was seen as an issue of autonomy in residential care where opt-in/out systems may be necessary to maintain respect for the autonomy of individual residents (Percival & Hanson 2006; Remmers 2010).

User autonomy can also be affected by the belief that developers, administrators or monitoring systems harbour behavioural expectations. Smart homes, telehealth and telecare have been shown to exhibit passive control over users, including the alteration of daily routines based on the presence of monitoring (Tiwari et al. 2010; Sanders et al. 2012) for example by sleeping at certain times or not leaving the house for fear of being viewed as wandering (Tiwari et al. 2010). Such alterations have been traced to the perception of a “watcher” on the “other side” of the monitor (Essén 2008), or the perception that the monitoring system is expecting behaviours within a “normal range.” The ‘expectations’ built into a system, or the patterns which define ‘normal’ and ‘abnormal’ behaviour, become very important in this context; developers exhibit passive control over the behaviours of users by defining physiological and behavioural norms (see: Section 3.4.1.4).

Inhibition of autonomy extends beyond behavioural control, with PHM influencing self-identification, particularly among dependent users who develop a reliance on PHM (Brey 2005; Friedewald et al. 2007). PHM can help care for individuals by reducing the need for the presence of a human carer, replaced instead by ‘always-on’ monitoring and emergency alerts. By providing a ‘safety net’ PHM can impede self-determination by reducing self-reliance (Percival & Hanson 2006; Remmers 2010). In other words, the perception that a carer will be alerted if something goes wrong may reduce feelings of personal responsibility for maintaining health (Fugger et al. 2007; Demiris 2009; Bowes et al. 2011). Dependent users may also

experience changes to their role in user-carer relationships—Kenner (2008) suggests carers can intervene in the life of the user based on PHM data, violating the user’s right to privacy and autonomy. Infringements are possible regardless of the intent of intervention. Medically beneficial interventions are not necessarily respectful of privacy or autonomy, as suggested by the tension characterising adoption of PHM (See: Section 3.3.2).

Autonomy, conceived of as a right to independence, may also be enhanced by PHM aimed to support the elderly and chronically ill with living independently at home. In a study of potential users, elderly and chronically ill individuals expressed a willingness to self-monitor critical bodily functions if it reduces the need for carer visits (Wilkowska et al. 2010, p.88). PHM enables patients in need of assistance to escape the “indignity” of being cared for by others (Gaul & Ziefle 2009, p.329). Conceptually, indignity can be connected to stigma derived from requiring care (Gaul & Ziefle 2009, p.330); to require support is to be perceived as ‘old’, ‘ill’ or ‘infirm’, and thus more dependent (Ziefle et al. 2011, p.410). PHM can promote independence by reducing the burden placed on carers, while enabling patients to choose a method of care which matches their values or desire for independent living, although an overriding ‘need’ for the technology to feel safe may dominate the decision to adopt PHM.

3.2.3 Safety

PHM was seen to enhance safety when it contributes to detection and treatment of ill health. One study identified a lack of contextual information in PHM data presented to physicians and nurses as a possible safety risk, potentially causing misdiagnosis (Kaplan & Litewka 2008). Systems are often promoted as protecting or enhancing the safety of users (Nordgren 2012), particularly among individuals with dementia and their carers (Lauriks et al. 2007). Safety appeared as a ‘goal’ that trumps ethical concerns, particularly in studies of dementia carer attitudes (Topo 2009; Landau, Werner, et al. 2010), which is troubling when monitoring individuals lacking the capacity to consent or choose preferred methods of care.¹⁸

3.2.3.1 Ethical Tradeoffs based on Technological Need

Safety was connected to a ‘need’ for PHM, particularly among elderly and chronically ill individuals (Melenhorst et al. 2004; Courtney 2008). Need is a multi-factored concept built

¹⁸ As an example of the bias towards safety in the literature, consider the contentious claims of Lauriks et al. (2007). It is not clear if the study included individuals with dementia in reaching the conclusion that “GPS systems are proven to result in feelings of enhanced safety and less fear and anxiety.” This conclusion appears to be based on the results of a single study, and cannot be generalised to all individuals with dementia.

upon internal and external perceptions of health and well-being, as well as the compatibility of PHM to the user's environment and current care regime (Courtney et al. 2008). Ethical issues caused by monitoring, such as a loss of privacy, can be justified by a 'need' for the technology derived from safety concerns related to health (Steele et al. 2009; Zwijsen et al. 2011). This type of justification is described as a 'tradeoff', meaning that the benefit of safety is worth the cost of privacy or other undesirable implications. The correlation between need and ethical concepts is, however, not always a negative tradeoff; an elderly user who 'needs' PHM to monitor his safety at home may also experience enhanced autonomy by delaying a move to residential care through monitoring (Essén 2008; Remmers 2010; McLean 2011; Townsend et al. 2011) or reducing the need for carer visits (Essén 2008; Ojasalo et al. 2010).

Tradeoffs were often seen between personal privacy and safety, particularly among the mentally impaired (Landau, Werner, et al. 2010; Ojasalo et al. 2010; Stowe & Harding 2010), as well as frail elderly (Melenhorst et al. 2004; Courtney 2008; Courtney et al. 2008; Steele et al. 2009) and chronically ill persons (Neild et al. 2004; Salih et al. 2011). These tradeoffs may be seen as a necessary part of aging, with increasing susceptibility to health problems (Steele et al. 2009), though this view should not be applied generally to associate 'aging' with reduced expectations of privacy, or to justify increasing violations of privacy in healthcare.

3.2.4 Obtrusiveness and Visibility

Obtrusiveness was identified as relevant to long-term acceptability of PHM (Demiris 2009; Demiris & Hensel 2009; Nefti et al. 2010; De Bleser et al. 2011; Townsend et al. 2011; Ziefle et al. 2011). Several studies employed a common framework of obtrusiveness in interviews and focus groups with users of smart home "assistive technologies" (Hensel et al. 2006; Demiris & Hensel 2009; Tiwari et al. 2010). The framework defines obtrusiveness, according to 22 subcategories, as "a summary evaluation by a person based on characteristics or effects associated with the technology that are perceived as undesirable and physically and/or psychologically prominent," meaning it is judged by the individual within a specific context (Hensel et al. 2006). Although obtrusiveness appeared frequently as a term in the reviewed literature, the studies using this framework were alone in having a clear definition. The framework alludes to the distinction between physical and mental obtrusiveness as seen in non-medical ambient intelligence applications (cf. Brey 2005). According to these studies, a sense of obtrusiveness may lead participants to subvert PHM, for example by not stepping on pressure sensors (Courtney et al. 2007).

The related concept of visibility is interpreted as the degree to which a PHM device is noticeable by the user and other individuals, at home and in public (Robinson et al. 2007; Essén 2008; Landau, Werner, et al. 2010; Wilkowska et al. 2010; van Hoof et al. 2011). Visibility differs from obtrusiveness in its emphasis on the public sphere. Characteristics affecting visibility include ease of use, size and weight (Landau, Werner, et al. 2010), suggesting a link to psychological and physical obtrusiveness. Reducing the visibility of PHM may be a desirable outcome according to developers (Fellbaum 2008) and users (Essén 2008; van Hoof et al. 2011), but it is not without problems.

The psychological disappearance of PHM can be problematic in two ways. While disappearance may initially promote acceptance of the technology and preserve the meaning or character of the home (Courtney 2008), users with cognitive impairment may eventually forget entirely about the monitoring equipment. This type of ‘covert’ monitoring raises questions of consent (Kenner 2008; Bowes et al. 2011), which was not recognised in all studies mentioning the phenomenon (e.g. van Hoof et al. 2011). The issue of consent extends to individuals entering the home of a monitored individual, which suggests the possibility of inadvertent monitoring (Neild et al. 2004). Whether users have a responsibility to inform guests of the presence of PHM remains an open question.

3.2.5 Stigma and Identity

PHM creates possibilities for a user to experience stigma, which can influence self-identity, for example by identifying as a ‘patient’ when wearing monitoring in public (e.g. Courtney 2008). Stigma is linked to the visibility of a system, and has implications for the identity of the user. The relationship must be approached from both public and private perspectives to reveal the source of stigma and effects on user identity.

From a public perspective, PHM that is visible to others can cause stigma, influencing self-esteem and self-identification as a patient. PHM was seen to cause feelings of frailty and perceptions of external judgment from others in residential care based on the public visibility of the device (Courtney 2008), although the problem could potentially be mitigated through aesthetic choices (cf. Wu et al. 2012) or community wide implementation (Courtney 2008). Attractive as the latter solution may be, it violates the principle that PHM applications should be customised to the user’s individualised needs to avoid “monitoring for monitoring’s sake” (Bowes et al. 2011), or pursuing monitoring as an end in itself (Coughlin et al. 2007; McLean

2011). Forcing monitoring upon residents without a need or desire for it would be disrespectful of their right to autonomy, making community wide implementations ethically problematic.

From a private perspective, the relationship between autonomy and identity is important. PHM can affect how user's self-identify if seen to represent frailty, dependence, illness or characteristics associated with ageing (Sanders et al. 2012). Changes to identity may be limited to PHM used to monitor chronic illnesses or health conditions associated with ageing, while being less likely with PHM used for preventative purposes (e.g. lifestyle monitors) or for monitoring acute conditions. By eliminating the opportunity to overcome obstacles associated with ageing, PHM eliminates experiences that contribute to "a new sense [of] the meaning of life" for the elderly (Remmers 2010). Even without technological reliance, systems can influence how a user's identity develops over time by automatically reporting risky or harmful behaviours indicative of frailty (Sanders et al. 2012). These activities are often hidden by elders wishing to control the image presented to outsiders (Percival & Hanson 2006), meaning PHM can erode the ability to manage public identity.

3.2.6 Social Isolation

Concern was seen regarding socially isolating users if the need for face-to-face interaction with GPs, professional and informal carers, friends and family is reduced where PHM is used for preventative monitoring or home care of the chronically ill and infirm (Demiris et al. 2004; Friedewald et al. 2007, p.26; Little & Briggs 2009; Stowe & Harding 2010; Tiwari et al. 2010; Sorell & Draper 2012; Wu et al. 2012). Isolation may occur if PHM is used to 'care' for patients in place of human carers as can be expected in efforts to reduce care costs and demand (Collste & Verweij 2012), jeopardising the health benefits of regular social interaction and physical touch (Chan et al. 2008). Isolation may be a necessary tradeoff if PHM is intended to enhance autonomy or independent living, as the latter cannot improve without a reduction in interference in behaviour (Sorell & Draper 2012, p.42), for example through carer visits.

Studies of the elderly have shown a concern that PHM will replace personal and social interactions (Chan et al. 2008; McLean 2011; Palm 2011; Zwijsen et al. 2011; Wu et al. 2012) rather than supplementing them. Contextual information may also be less available when assessing a patient's condition (Percival & Hanson 2006), suggesting that the quality of diagnosis and care is diminished by the loss of face-to-face encounters. Sufficiently complex

emerging applications may be able to monitor enough contextual characteristics to provide an accurate picture of the person's physical and mental state (Pentland 2009; Sadri 2011), but the ability of extant monitoring systems to correctly assess complex emotional and social conditions indicating distress is questionable.

Assistive homecare robots (Wu et al. 2012) and social networking features (Percival & Hanson 2006) have been proposed as solutions to the problem of social isolation. Classifying these interventions as solutions rests on the questionable assumption that human interaction can be adequately replaced by technological interventions. According to Palm (2011), if PHM is viewed by professional care providers as a replacement for social interaction among dependent patients, morally unjustifiable burdens may be placed on “informal carers” (family members, relatives, spouses) that are increasingly responsible for providing care and face-to-face interaction, while also suffering the social and physiological burdens of these roles (cf. Williams 2002, p.143). Furthermore, although social networking can reduce feelings of isolation (cf. Feenberg et al. 1996), in doing so it forces users to give up personal information to regain the social interaction lost to PHM.

Social isolation may be mitigated by a feeling of increased connectivity to care services mediated by PHM, for example through quicker access to GPs or data custodians (Dhukaram et al. 2011; Ure et al. 2012). Although helpful, connectivity is not equivalent to face-to-face encounters in terms of physical touch and awareness of context, and should not be seen as a like-for-like replacement when assessing PHM.

3.2.7 Delivery of Care

Relatively few sources discussed the impact of PHM on medical personnel. Two studies examining carers and power relationships concluded that “surveillance” in a social care setting can lead to new power relationships among professional carers and recipients, affecting interactions during visits (Kenner 2008; Vuokko 2008). If granted access to monitoring data carers can ensure patients are following recommended medical interventions or detect risky behaviours, potentially disrespecting the patient’s right to privacy and self-determination (Remmers 2010). Concerns were also expressed over the impact on professional carers, including the collection of data without the knowledge of patients/workers in public locations, such as hospitals (Tentori et al. 2006), or activity and location tracking of medical personnel (Ahamed, Talukder & Kameas 2007, p.208). A connection with social isolation was seen in the

worry that PHM used to replace human interaction to prioritise care and reduce costs will limit carers to interventions recommended by PHM, and lessen opportunities for social contact with patients (Collste & Verweij 2012). PHM is also perceived to threaten job security among home care workers if used as surveillance to expose human error (Tiwari et al. 2010; Collste & Verweij 2012), or to add to workloads or complicate work routines (Tiwari et al. 2010). Questions over the ethical acceptability of workplace surveillance within healthcare are raised; workers are deserving of some level of privacy (cf. Lankshear & Mason 2001), yet this right should be balanced against the need for oversight and patient safety.

The influx of PHM data could also cause “information overload” for medical professionals, who may be obligated to review all available information about a patient (Kaplan & Litewka 2008). Alternatively, monitoring data may be useful to practitioners but lack practical value to users, which may jeopardise long-term use (Beaudin et al. 2006a), adding tension to the provider-patient relationship and perhaps wasting valuable healthcare resources. The implications for healthcare professionals expose the complex network of professional and personal relationships in which PHM will operate.

3.2.8 Risk

‘Risk’ was treated as an independent concept in the search terminology, with the hope that it would produce sources discussing normative aspects of PHM outside of the discussion of ethics, (e.g. Morris 2000; Hilty et al. 2004; Busnel & Giroux 2010; Kastenhofer 2011). In contrast to expectations, the treatment of risk in the reviewed literature is mostly limited to privacy and security implications of PHM (Pentland 2009; Lim et al. 2010; Nefti et al. 2010; Sadri 2011) or risk taking behaviours of seniors (Percival & Hanson 2006; Remmers 2010). Risk was rarely conceptualised as a future-oriented concept, as seen in risk assessments of future scenarios (e.g. Friedewald et al. 2007; Kastenhofer 2011). The inclusion of ‘risk’ as an independent concept in the search terminology did not contribute content beyond the themes addressed. The exception was a risk assessment identifying normative aspects of pervasive computing including environmental and human effects of non-ionizing radiation, stress imposed on users, restriction of consumers' and patients' freedom of choice, threats to ecological sustainability, and dissipation of responsibility in computer-controlled environments (Hilty et al. 2004).

3.2.9 Medicalisation

Medicalisation rarely appeared as a concept in the reviewed literature, although several studies described issues that can be interpreted as medicalisation of the home environment. Borrowing a definition from outside the reviewed literature, medicalisation is defined as transformation of “aspects of life previously outside the jurisdiction of medicine” into medical problems (Clarke et al. 2003, p.161). In the context of the home, medicalisation occurs when a user is reminded of a health condition due to the presence of a monitoring system. In this sense, PHM introduces a medical aspect into the “experiences and meaning of home” (Courtney 2008), which is otherwise seen as a place where privacy and identity are protected (Courtney et al. 2008). Multiple studies remind PHM developers of their responsibility to address medicalisation of the home (Chan et al. 2008; Demiris & Hensel 2009; Gentry 2009; Bowes et al. 2011). A risk for developers is to view the home environment as a blank canvas for medical monitoring technologies, or “just a machine” (Gentry 2009). In this case the home could be turned into a medical environment or “de facto intensive care unit,” eliminating the public-private divide between home and “brick and mortar” medical environments (Chan et al. 2008; Demiris & Hensel 2009; Bowes et al. 2011), turning the home into a ‘virtual hospital’ for all its inhabitants, not only users.

The potential for medicalisation goes beyond the home. Proliferation of PHM data could lead to the medicalisation of the lives of users, in which previously unnoticed fluctuations in physiological parameters and behaviours throughout the day enter the attention of users, reminding them of their condition (Dhukaram et al. 2011; Sanders et al. 2012). Clinicians in one study suggested they would be reluctant to recommend PHM due to “fear their patients will overreact” to the collected data, whereas patients fear being diagnosed with a medical condition that would have otherwise gone unnoticed (Beaudin et al. 2006b). With that said, an increase in the availability of personalised medical information could also lead to a better working relationship between patient and physician, for example through the reinforcement of healthy habits when a “weight loss plateau” is encountered (Beaudin et al. 2006b). Effects such as these stemming from placing greater attention on user health conditions can be understood as a type of ‘personal medicalisation’ of the user’s body or life, rather than the home.

3.3 Critical Analysis of the Discourse¹⁹

The discourse is filled with descriptions and analysis of ethical implications for specific applications, contexts of use and users of PHM. While themes were identified in the discourse, technology-level analysis adopting a holistic view of PHM as an array of related applications and artefacts (cf. Brey 2011) was uncommon (cf. Brey 2005; Palm 2011; Sadri 2011). The application-led approach is a commendable pragmatic approach to ethical analysis, useful for assessing implications of specific uses; indeed, much of applied ethics follows this course (e.g. Jonsen 2007). However, the specificity of the cases considered meant that gaps are inevitable in the discourse, based on a lack of in-depth theoretical analysis and consideration of technology-level implications. In some cases, the discourse as a whole fails in terms of its scope, for example with inadequate attention paid to ethical implications for particular applications or demographics of potential users. Many sources also lack a critical edge, for example in not questioning the inevitability of ethical implications evident in user attitudes towards adopting PHM. Similarly, existing mechanisms of preventing ethical harm, such as data protection laws and informed consent, are uncritically accepted as adequate without questioning the need for refinement or updating to protect against implications of PHM. Finally, the usage of ethical concepts such as privacy and autonomy was often without clear theoretically informed definitions, undermining the validity and scope of findings.

3.3.1 Technical and Demographic Limitations of Scope

In the discourse environmental monitors for the elderly have received a majority of attention, with Mobile and In-Vivo Monitors given comparatively little (see: Appendix 1 Table 1.1). Even with a large share of the discourse, the discussion of ethical issues of Environmental Monitors was often superficial (cf. Niemeijer et al. 2010; Zwijsen et al. 2011), lacking reference to underlying concepts or theories. It could be argued that despite the variety of PHM applications and technical features, the ethical implications are more or less common across the field, so the technical gaps are not problematic. However, as suggested by the problems faced by technologically deterministic accounts of medical technologies (e.g. Timmermans & Berg 2003) as well as the conclusions reached in PHM-Ethics and ETICA, it cannot be assumed that technologies with similar technological characteristics will give rise to identical ethical implications across varying contexts, in which the technology and its implications are given meaning by stakeholders with varying backgrounds and moral values. Features of specific

¹⁹ The term 'critical analysis' is not an appeal to critical theory (e.g. (Stahl 2008); it refers only to an analysis with criticism.

contexts, such as user values and expectations of care, change how ethical implications are experienced.

It follows that for a discourse dominated by application-specific analysis to provide sufficient understanding of the technology, as many categories of applications (see: Chapter 2), contexts of use (e.g. residential care, cohabited homes) and users (e.g. patient groups) need to be assessed as possible. The discourse fails to give adequate attention to the range of demographic groups being targeted by PHM, particularly the non-elderly, healthy and acute patients, which is problematic if ethical implications are unique to specific contexts, especially when considering that applications aimed at different demographics possess different technical features and ends. Elderly and chronically ill users received the majority of attention in the discourse (see: Appendix 1 Table 1.2). In many cases PHM applications are designed with a specific age-group in mind, so the focus on the elderly is unsurprising considering the wealth of emerging smart home systems which respond to the growing burden placed on healthcare resources by individuals in the later stages of life (Remmers 2010; Palm 2011). Although it may be easiest to identify potential ethical issues in applications operating in the private sphere for the benefit of a 'vulnerable' population (e.g. Kenner 2008; McLean 2011), non-elderly users deserve more attention because the goals of PHM (e.g. preventative monitoring, chronic illness management) which PHM responds to are not age-specific.

Many studies of the elderly treat advanced age as a chronic illness (cf. Agree et al. 2005; Percival & Hanson 2006; Courtney 2008; Courtney et al. 2008; Dorsten et al. 2009; Tiwari et al. 2010) rather than as a normal process of life (Remmers 2010).²⁰ In the discourse users are treated as patients adopting PHM in response to a health condition, which ignores the potential of PHM for preventative and lifestyle monitoring among healthy users. Only five sources address implications of these uses among non-elderly and healthy users (Beaudin et al. 2006b; Monahan & Wall 2007; Gaul & Ziefle 2009; Pentland 2009; Ziefle et al. 2011), despite these groups potentially being the largest (Dittmar et al. 1997; De Rossi et al. 2000; Lymberis 2003; Ganti et al. 2010). The potential implications of secondary uses of PHM data alone justifies further research into healthy users (cf. Cios & William Moore 2002; Monahan & Wall 2007).

²⁰ The treatment of ageing as a medical condition, by which elderly people are described in "ageist" terms as frail or vulnerable, is not unique to the discussion of PHM (e.g. McLean 2011).

Secondary stakeholders (non-users) including medical personnel (Percival & Hanson 2006; Beaudin et al. 2006b; Melander-Wikman et al. 2007; Vuokko 2008; Landau, Auslander, et al. 2010; Niemeijer et al. 2010; Tiwari et al. 2010; Agrafioti et al. 2011; Mittelstadt et al. 2011), family carers (Percival & Hanson 2006; Mahoney et al. 2007; Robinson et al. 2007; Landau, Auslander, et al. 2010; Palm 2011; Rigaud et al. 2011), and non-adopters were also given insufficient treatment in the literature (Palm 2011), despite serious potential effects on the relationships between users and non-users. Non-adopters were entirely ignored as stakeholders in the literature, despite the potential for PHM to affect them indirectly, for example if healthcare commissioning is based on monitoring data.

Clearly, the scope of stakeholders and interests considered in the literature needs expansion. Generalising findings from studies involving only elderly and chronically ill individuals to non-elderly, healthy and acute users is problematic given variance in acceptance motives within age and health demographics (cf. Gaul & Ziefle 2009; Ziefle et al. 2011), as well as context and application specific implications. As a result, demographic groups must be treated in future discourse as increasingly heterogeneous in terms of their responses to PHM, with non-elderly, healthy and acute users requiring more attention.

3.3.2 The Inevitability of Ethical Tradeoffs

Beyond the nine ethical themes identified, a common trait was found in the moral reasoning among participants in several studies. A form of moral bargaining was seen which revealed an ‘inherent duality’ in participants responding to the ethical challenges presented by PHM (Melenhorst et al. 2004; Mahoney et al. 2007; Courtney 2008; Demiris et al. 2008; Ding et al. 2011; Zwijsen et al. 2011). The inherent duality of participant’s moral views reveals the complexity of the ethical tradeoffs faced by individuals choosing to adopt PHM for themselves or others. The belief that the technology would fulfil an important need that outweighs its downsides was common, for example with privacy concerns overridden by technological need based on safety concerns. In this context deliberation was described as a “pragmatic approach” to adopting PHM, by which privacy implications are recognised by adopters but seen as less important than the safety need filled by the technology (Courtney et al. 2008, p.198).

The inherent duality seen in moral deliberation (cf. Niemeijer et al. 2011) reveals a tension in the decision to adopt PHM by which users and third parties find appropriate tradeoffs

between moral values, technological benefits and burdens. Many such conflicts were seen, including:

- Freedom and Safety (e.g. Gammon et al. 2009; Landau, Werner, et al. 2010; Landau, Auslander, et al. 2010; Palm 2011; Zwijsen et al. 2011)
- Privacy and Autonomy (e.g. Melenhorst et al. 2004; Essén 2008; Steele et al. 2009; Remmers 2010; Townsend et al. 2011)
- Stigma and Safety (e.g. Melenhorst et al. 2004; Courtney 2008; Wu et al. 2012)
- Autonomy and Safety (e.g. Percival & Hanson 2006; Kenner 2008; Gaul & Ziefle 2009; Wilkowska et al. 2010; Bowes et al. 2011; Ziefle et al. 2011)
- Privacy and Safety (e.g. Melenhorst et al. 2004; Neild et al. 2004; Courtney 2008; Courtney et al. 2008; Ojasalo et al. 2010; Zwijsen et al. 2011)
- Medicalisation and Safety (e.g. Chan et al. 2008; Courtney 2008; Demiris & Hensel 2009; Bowes et al. 2011)

These examples characterise the moral reasoning of users in adopting PHM as an ethical tradeoff between conflicting goods by stakeholders, in which benefits are enjoyed through the acceptance of undesirable outcomes.

Accepting this form of moral reasoning in which the acceptability of PHM is seen as a balance between privacy, autonomy and safety (cf. Mittelstadt et al. 2011) is problematic. Deliberation is not dichotomous by necessity, with two values coming into direct conflict; deliberation will likely involve a range of ethical concepts and moral values, informed by the stakeholder's individual background. The implications of PHM are far more complex than allowed by these three familiar concepts which dominated the discourse (see: Appendix 1 Table 1.3). This type of reasoning may be encouraged by the tendency among developers, evident in the morally loaded language used to advertise their products (e.g. Nordgren 2012), to embrace a technologically deterministic attitude by which PHM is believed to cause pre-determined, typically desirable outcomes (Fugger et al. 2007; van Hoof et al. 2011; Nordgren 2012), regardless of the context of use. A similar attitude is taken by researchers who see PHM as 'morally neutral' because users have the opportunity to rank different goods in an ethical tradeoff prior to adoption (e.g. Welsh et al. 2003; Martin et al. 2007).

The acceptance of a dichotomous view of adoption, by which ethical tradeoffs are a necessity, implies that nothing can be done by developers or service providers to lessen the burdens for

users. The fact that this view is so common in the discourse suggests that users fail to see possibilities for impacting on the design and deployment of PHM to better meet their values (e.g. Joss & Bellucci 2002; Friedman et al. 2008), for example regarding expectations of privacy.

3.3.2.1 Context-Sensitivity and Ethical Tradeoffs

The dominance of ethical tradeoffs in adoption thinking is also problematic in the sense that it presents a dichotomous positive/negative view of PHM, by which an application is generically 'privacy enhancing' or 'autonomy inhibiting' for users across all contexts of use. The tradeoff can be formulated as 'adopting application X causes desirable effect Y and undesirable effect Z'. Approaching tradeoffs in this deterministic fashion is problematic if ethical concepts and implications are given meaning by stakeholders in specific contexts (cf. Nissenbaum 2004) (see: Section 1.2.6), shaped by the user's values, medical needs and expectations of care, as well as the effect of the technology on user expectations (cf. Latour & Venn 2002); this is why the same application can be privacy enhancing in one context, and inhibiting in another (see: Figure 3.1). It is therefore problematic to rely solely on preconceived definitions, specifications and hierarchies of ethical concepts in empirical research (Clouser & Gert 1990; Martin et al. 2007), or to assume the existence of a 'common morality' between researcher and participants. Instead, a context-sensitive approach is required in which ethical concepts are given meaning by the stakeholders of a specific context.

Figure 3.1 - Smart Homes and User-Specific Implications

As an example of context-specificity, consider a smart home system designed to constantly monitor an elderly user to detect falls and other emergencies requiring carer intervention (cf. Chan et al., 2008). User A welcomes the system in his home because it means that his daughter, who acts as his primary carer, does not need to visit as frequently to 'check up' on him, making sure (for example) that he has not had a fall or taken ill. The system frees up the time of the daughter to pursue personal interests and projects, while helping User A regain his sense of independence which was lost when he started to require care on a regular basis from his daughter. Although having similar care needs, User B hates the idea of having PHM in his home, because he values his privacy above all else. While he understands the need to be 'looked after' by someone, he much prefers visits from his family members and friends because it gives him time to socialise and enjoy the company of others. With that said, he knows that when he shuts the door behind them, his house becomes his private space once again. The idea of an 'always-on' monitoring system bothers him greatly because he loses the opportunity to 'close the door' on the outside world. As a result, User B feels that PHM would make him feel 'watched' in his own home (cf. Percival and Hanson, 2006), and change how he acted as a result.

Context-sensitivity was missing from much of the discourse, with the meaning of ethical concepts derived from the researcher's preconceptions rather than stakeholders in the context under study. Typical of these studies was a superficial discussion of ethical theory and concepts (e.g. Welsh et al. 2003; Coughlin et al. 2007; Fugger et al. 2007; Lauriks et al. 2007; Gammon et al. 2009; Stowe & Harding 2010; Tiwari et al. 2010; Ziefle & Röcker 2010; Frisardi & Imbimbo 2011; van Hoof et al. 2011; Kovach et al. 2011; Rigaud et al. 2011), ignoring the need to explore the context-specific meaning of principles and concepts (e.g. Fellbaum 2008, p.161). Without engaging participants in a process of interpretation in which norms are "specified" (cf. Richardson 1990), conclusions reached in such 'common morality' studies remain presumptive, based not on the beliefs of the participants but the preconceptions of the researchers. The failure of these studies raises doubts over the legitimacy of pragmatic conclusions derived from such top-down research.

This is not to suggest that ethical theory and principles have no place in ethical analysis, or that examination of specific uses alone can provide sufficient understanding of moral potential of an emerging technology. Rather, the point is that a common morality between researcher and user, or developer and user, by which concepts and implications carry the same meaning across contexts, cannot be assumed. The studies mentioned here were characterised by a lack of sensitivity to the values and meaning given to ethical concepts by users, meaning they could benefit from further reflection on how ethical concepts were defined.

3.3.3 Difficulties of Adapting Protection Mechanisms

As with all emerging ICTs, it is difficult to predict the future ethical implications of PHM prior to widespread use. Known as the Collingridge dilemma (1980), this problem is the result of the complexity of producing "accurate and meaningful technological forecasts" (Palm 2011) representing complex contexts of use. This problem is especially applicable to PHM, as it involves unprecedented socio-technological interactions with uncertain consequences. These uncertainties suggest a proactive social response is necessary to avoid foreseeable ethical harm. In this context existing mechanisms which protect users from ethical harm achieve new importance, yet they may prove insufficient in the face of the complex uncertainties presented by PHM.

3.3.3.1 *Informed Consent*

Of the existing protection mechanisms, informed consent received the most attention in the reviewed literature (see: Appendix 1 Table 1.3), although there was a failure to recognise the difficulties of granting informed consent due to the uncertainty of emerging PHM implications. The primary difficulty is that a reliable account of the ethical implications or risks of using PHM cannot be given prior to use (Demiris & Hensel 2009; Stowe & Harding 2010), particularly concerning secondary uses revealed through data mining (Cios & William Moore 2002). It is therefore difficult if not impossible to meet practical standards of informed consent in medical practice, such as those set out by the UK's General Medical Council (GMC) which require that the user be given all relevant information about an intervention including their diagnosis, how the diagnosis was reached including unknown factors and assumptions, the design and purpose of the intervention, known risks and benefits, the likelihood of success, alternative treatment options, who will be involved in the intervention and any conflicts of interest. The information must be tailored to the needs of the patient, taking account for the patient's level of understanding, the type of information necessary to make an informed decision, as well as clinical or other factors the patient may find significant. However, it is ultimately the responsibility of the patient to determine the required information, ask questions and to make a decision he considers reasonable (General Medical Council 2008).

For PHM, it is doubtful that the risks and benefits of future uses could be predicted with sufficient reliability to provide a confident account to the user, due to the complex relationship between context of use and outcomes. An intertwined relationship between societies and technologies with a two-way process of cause and effect has been explored in recent years by researchers in social informatics (Kling 2007). Under this model, the effects of a technology will be determined by the user and social context in which it is deployed, meaning the effects will change as the context changes. If this approach is correct, it is impossible to accurately predict the future risks and benefits to a potential user of PHM because contexts and uses of the device will change over time.²¹ This is not to say technological forecasting or proactive ethics is impossible, but rather that the ideal of informed consent requires revision in response to the inherent uncertainty of emerging technologies.

²¹ Even if this limitation is overcome and the ideals of informed consent are otherwise met, there is no 'right' way to present implicitly normative information about risks and benefits to patients in every situation (Molewijk et al. 2003) unless the normative background of every piece of information and judgment involved can be made explicit, which would place a significant burden on physicians.

This uncertainty need not cause a practical problem for practical versions of informed consent used in medical practice, such as the GMC's (2008), so long as the user is free to determine the volume and quality of risk/benefit information required to make a reasonable decision. With that said, the importance of identifying the shortcomings of the risk/benefit information during the consent process is to ensure the unpredictable effects of a technology and its social context are communicated to potential users of PHM. Considering the normatively loaded language used by developers in advertising PHM (Nordgren 2012), it is imperative that potential users receive information on the limitations of predicting effects of adopting PHM to avoid creating unjustified and unrealistic expectations among users.

3.3.3.1.1 Problems of Proxy Consent

The decision among carers to adopt PHM for dependent users and children is often characterised by ethical tradeoffs in the discourse (Gammon et al. 2009; Landau, Auslander, et al. 2010; Palm 2011), hinting at a potential problem with proxy consent. Previous studies (Mozley et al. 1999; Nygard 2006; Hellström et al. 2007; Cubit 2010) have demonstrated incongruity between carer and dependent values, suggesting that the exclusion of individuals with impaired intellects from the design and governance of PHM may inadvertently produce applications ill-suited to the values of dependent patients. Questions about the integrity of proxy consent for adoption of PHM are also raised. For instance, GPS tracking devices may be chosen by carers to protect the safety of mentally impaired individuals. However, early Alzheimer's patients have been shown to fear the loss of autonomy more than death (Cohen-Almagor 1996), so it seems counterintuitive to use autonomy-inhibiting devices such as tracking technologies to ensure their safety. This example hints at the unique problems that will be faced with proxy consent for PHM, which exceed previously identified issues with proxy consent (cf. Cubit 2010).

3.3.3.2 Data Protection Legislation

The provisions offered in forthcoming legislation which govern the collection, processing and storage of personal health data deserve anticipatory analysis because data protection legislation contribute significantly to the legal and ethical frameworks in which future development and deployment occur (Kosta et al. 2010). Systems, developers and data handlers abiding by relevant legislation are seen as 'responsible', 'ethical' or respectful of the rights of users. A 'policy vacuum' (Moor 1985) may exist in which DP legislation is insufficient to protect users against the privacy implications of PHM. In the EU the Data Protection

Directive of 1995 personal data related to health is protected as ‘sensitive personal data’, although it is unclear whether all of the data collected by PHM would qualify. Similarly under the UK’s Data Protection Act of 1998 PHM data regarding user behaviours may not be classified as “sensitive personal data” because of its indirect connection to the health of the user, in which case it would be afforded less protection than given to other types of medical data (see: Appendix A2.1).

These problems will be moot in the near future when the EU General Data Protection Regulation comes into full effect in 2016, replacing national data protection legislation throughout the EU. Personal data is defined as any data which can identify the user through name, address, location, identification number, pseudonym including online identifiers, as well as physical, physiological, genetic, mental, economic, cultural and social identifiers (European Commission 2012, Article 4). The Regulation clarifies the ambiguities of prior legislation in that behavioural data is considered a ‘special category of personal data’ which can only be used in the ‘legitimate interests’ of the user (European Commission 2012, Article 9), assuming a link between behaviour and health can be found. With this said, misuses may be justifiable through a broad interpretation of the ‘legitimate interests’ of the user, and are more likely to occur when users are unable to exercise their privacy rights²² due to ignorance of the extent of data held.²³

3.3.4 Privacy and the Lack of Context-Sensitivity

Throughout the discourse, usage of ethical concepts without explanation of their meaning or reference to underlying theoretical frameworks was common (see: Section 3.2). Nowhere was this more obvious than in the discussion of privacy. Privacy can be seen as intrinsically morally valuable, or deriving its value from related rights or ethical concepts, especially autonomy or freedom (e.g. Schoeman 1984; van den Hoven 2008, p.302). Although the precise content of

²² In the literature reference was often made to the privacy rights of individuals (see: Section 3.2.1.2.2). The independent existence of such rights, which has long been questioned by moral philosophers (cf. MacIntyre 2007, p.69), is immaterial to importance of weaknesses identified with data protection mechanisms; so long as such rights are treated as real in international agreements and national law, they form a pragmatic ‘first line of defence’ against privacy violations and should be taken seriously in proactive ethical analysis.

²³ The legal implications of PHM and legal uses of PHM data are outside of the scope of this research project. It is however recognised that data protection legislation is particularly relevant as a tool for protecting the privacy rights of users, and limiting how PHM data can be used by third parties, including for social surveillance (cf. Lyon, 2003). On this basis a more detailed analysis of the implications of specific provisions of the forthcoming EU General Data Protection Regulation for the privacy rights of PHM users is offered in Appendix A2.2.

the concept, which can be construed as “a right, a condition, or an aspect of human dignity” (van den Hoven 2008, 302), remains fiercely debated, many actions which affect privacy can be identified without a definitive or clearly explained understanding of the concept. In the discourse this approach was common, which created uncertainty over the nature of privacy violations apparently mitigated by advances in security architecture and design of PHM systems. To understand why privacy analysis without a theoretical framework is problematic, it is necessary to first define how the concept can be understood in relation to PHM systems capable of monitoring myriad ‘private’ spaces and bodies.

Helen Nissenbaum’s theory of contextual integrity explores the meaning of context-specificity in connection with norms of privacy (Nissenbaum 2004). According to her theory, which is limited to data privacy for individuals but can be reasonably extended to cover aspects of personal privacy, expectations of privacy are determined by norms which are created in the multitude of contexts and relationships entered into in social life. Contexts are part of nearly all aspects of life, including “things that we do, events that occur, transactions that take place,” which implies that contexts in which “anything goes” in terms of privacy or dissemination of information, as seen (for example) in dichotomies such as ‘public’ and ‘private’ spaces, do not exist. Contexts vary in size, from broad contexts of education, medicine or politics, to single events or locations such as dentist visits, shopping online or walking in a park (Nissenbaum 2004, 119). No matter the size, “each of these...contexts involves, indeed may even be defined by, a distinct set of norms, which governs its various aspects such as roles, expectations, actions and practices.” Furthermore, norms need not be rigidly defined to exist: “implicit, variable and incomplete” norms are as important as highly regimented codes of conduct (Nissenbaum 2004, p.119), although the likelihood of violating such transient norms may increase when they are not obvious, meaning a shared understanding of the content of the norm does not exist between stakeholders.

Norms are relative to specific contexts, but may draw upon (universal) ethical theories, principles or concepts for justification (Nissenbaum 2004, pp.128–9). Norms can be defined with reference to various ‘privacy-enhancing borders’, which suggest specific barriers between people and spaces which PHM may violate: natural borders, such as physical objects (e.g. walls, clothes, closed doors) which prevent intrusions; social borders, or social relationships which dictate different expectations of privacy to be respected by people in different roles; and spatial and temporal borders, which are violated when information is isolated from the

space, time or context in which it was created (Marx 2001, p.158). Each of these borders can be violated by PHM, which can enable 'always-on' monitoring of physical spaces or bodily functions considered private by the user, and creates data which may be shared and reinterpreted in social and professional relationships not consented to by the user.

Nissenbaum suggests that two types of information privacy-related norms exist: those related to the appropriateness, or types, of information revealed to specific persons, and those restricting the dissemination of information (Nissenbaum 2004, p.120). Norms governing aspects of personal privacy and appropriate uses of information need to be added to extend Nissenbaum's theory to aspects of personal privacy (see: Section 3.2.1.2), such as norms which restrict physical access to a person (Marx 2001), define physical and social borders affecting access to data and permissibility of monitoring, or limit access to the user and his data in terms of social/professional relationships and roles. The latter is necessary when information revealed in a particular sphere or for a particular purpose is transferred or used for another (cf. Walzer 1983; Schoeman 1984). If privacy norms are context-relative, it follows that treating information according to norms influential in other contexts constitutes a violation of privacy (Nissenbaum 2004, p.127). Respecting privacy, then, requires understanding the content of privacy norms within the specific context in which a technology is used which collects and shares personal data.²⁴

The meaning of context-specific privacy norms vary "across cultures, contexts, kinds of persons and social categories" (Marx 2001, p.160), suggesting the conception of privacy concepts, such as public and private spaces, as acontextual is incorrect (e.g. the idea that the bathroom is always a private place across all cultures). To correct this tendency towards acontextual understanding, norms of privacy should be conceived as attached to individuals, not spaces, meaning norms are always in effect even in 'public' spaces. Telehealth, and PHM by extension, has been recognised to blur such boundaries between public and private spaces (e.g. Kaplan & Litewka 2008, p.409). However, conceptualising spaces in terms of privacy-enhancing borders, as opposed to distinctly public or private spaces, provides a better framework for understanding how monitoring can violate norms of privacy bound to barriers which limit acceptable activities in physical spaces, social, spatial and temporal relationships. It is therefore not self-evident that the privacy norms influential in existing patient-provider,

²⁴ Violations of context-specific norms may however be justifiable, for example when information is not readily available in an emergency, when sharing parts of a patient's medical record with first responders is necessary.

family-patient and developer-user relationships are appropriate in the context of PHM which bridges the gap between all three.

3.3.4.1 Privacy Myopia in Development

Privacy was rarely treated as a concept defined by context-specific norms in the discourse. Instead, the discourse overwhelmingly addresses protection of data privacy through security measures, where norms embedded in security architecture are taken to assure privacy protection. This is especially true of sources discussing the development of PHM systems and underlying security architecture (e.g. Stuart et al. 2008; Garcia-Morchon et al. 2009; Acharya 2010; Fragopoulos et al. 2010; Lim et al. 2010; Elkhodr et al. 2011; Garcia-Morchon et al. 2011; Salih et al. 2011), of which only four mention aspects of personal privacy (Neild et al. 2004; Pallapa et al. 2007; Bagüés et al. 2007b). While other types of sources addressed personal privacy, few references were found to background normative theory or theories of privacy. In many sources discussion of privacy, risk and related concepts was very brief, limited to few sentences or paragraphs, although some longer discussions were found outside development discourses (e.g. Brey 2005; Friedewald et al. 2007; Gaul & Ziefle 2009; Little & Briggs 2009; Remmers 2010; Ziefle et al. 2011). Privacy was often seen as a hurdle to be overcome to make systems acceptable to users by protecting their right to control their data (cf. Zwijsen et al. 2011), ignoring theoretical discourse around the concept.

Explicit definitions and discussions acknowledging the conceptual complexity of privacy were scarce in security or development-oriented literature²⁵, suggesting that systems are being designed and secured under the impression that privacy exists conceptually apart from specific contexts of use. This approach risks presenting systems as ‘privacy-enhancing’ (cf. Subramaniam et al. 2010) which are merely technically secure: “the idea is tempting: once we solve security, that is, once we are able to achieve authenticity and trusted communications, privacy will be a by-product that follows inevitably from a secure environment” (Langheinrich 2001). This security-oriented approach, reflected in the security and development literature, is deterministic in the sense that privacy is ‘built-in’ to systems, regardless of the context of use. This ‘top-down’ approach to privacy eliminates the experience of the user from the equation; privacy flows from the system to the user. Conceived as such, privacy is something that can be designed for without context-sensitive understanding of the expectations and norms valued by stakeholders.

²⁵ Of the 81 sources mentioning privacy, only 27 explicitly defined privacy or risk.

Another example of a myopic view adopted in the literature was the limited attention given to risk, for which a single perspective was present in the literature. In the few sources discussing risk factors of PHM, 'risk' was limited to the external—environmental factors pose a 'risk' for humans. Risk conceptualised as an internal factor, by which aspects of the body, genetics, behaviours or demographics place a person 'at risk' (cf. Lupton 1995, pp.77–8), was not addressed in the reviewed literature. This limitation will prove important in assessing the potential for PHM to socially categorise users by degrees of medical risk (see: Section 4.4.3)

The myopic character of the discourse reveals two significant gaps in the literature: (1) system and security developers fail to consider the role of the user and the effects of context-specific norms in privacy and related concepts (e.g. security, trust, confidentiality); and (2) aspects of (personal) privacy which cannot be addressed through system and security development receive comparatively little attention. These gaps suggest a disconnect between theoretical and applied (e.g. development) privacy discourses, in which theoretical development of privacy as a normative concept fails to inform development of PHM systems and underlying security architecture.

The myopic conception of privacy, by which privacy is reduced merely to control of data, risks simplifying future discourse, design and governance of PHM by ignoring personal, context-sensitive aspects of privacy. The discourse risks devaluing experiences of users falling outside of the narrow scope of privacy (defined in terms of data). Furthermore, it is problematic to claim that a PHM system or security mechanism is 'privacy-enhancing' (e.g. Pallapa et al. 2007; Garcia-Morchon et al. 2009) without demonstrating awareness of the conceptual complexity of privacy, and underlying theories of privacy. The need to expand the scope of the discourse has been recognised (Caine 2009), but remains largely unrealised as evidenced by the relatively few sources which provide in-depth discussions of aspects of privacy beyond security or data control.

This feature of the discourse may be a result of application developers lacking expertise in security (Busnel & Giroux 2010), privacy and ethical theory, while simultaneously failing to acknowledge research in these areas.²⁶ This is not to suggest that developers need to engage

²⁶ The limitation of privacy to data control, dissemination and security aspects by developers matches Westin's influential conception of privacy as the right of individuals "to control, edit, manage, and delete information about them[selves] and decide when, how, and to what extent information is communicated to others" (Westin 1970). The social dimension of Westin's definition, by which privacy

in theorising, especially in reporting on new systems, security measures and frameworks in conference proceedings and academic journals. Rather, what was lacking from ‘applied’ discussions in the reviewed literature was *awareness* of the complexity of privacy, security and risk, and the ethical and social scientific works which demonstrate the difficulties associated with ‘universal’, acontextual conceptions of privacy (cf. Nissenbaum 2004). The literature suggests developers understand privacy one-dimensionally: privacy is control over data about oneself, and is guaranteed through security mechanisms. If this simplified conception becomes embedded in system design, users face a future of ‘privacy enhancing’ health monitoring systems which may fail to meet their privacy expectations in practice. To mitigate this risk²⁷, developers and regulators need to better explain their conception(s) of privacy and its theoretical foundations, and identify how it is translated into system design. Furthermore, achieving a context-sensitive understanding of privacy requires understanding attitudes and expectations of stakeholders (McLean 2011), as well as practice-internal norms (cf. Nissenbaum 2004; MacIntyre 2007) of information dissemination and fair usage unique to the context(s) in which a particular PHM application will be used. Empirical research (cf. Gaul & Ziefle 2009; Little & Briggs 2009; Ziefle et al. 2011) and participatory design methods (cf. Joss & Bellucci 2002; Genus & Coles 2005) which address these needs are readily available.

3.3.4.1.1 The Capacity to Breach Privacy Borders

Concerns relating to context-specific norms of privacy also extend to the quantity and quality of data collected. PHM extends the temporal and spatial limitations of personal health data collection and storage. Users can be monitored and data recorded longitudinally, revealing information about behaviours, physiological parameters, mental states and consumption (Bohn et al. 2005, p.11; Brey 2005). PHM extends the *types* and *extent* of information available about users for subsequent searching, categorisation and mining, which has not occurred in the past because technologies to create similar longitudinal health data have not been available. It is unclear, then, how the extensive digitisation and storage of seemingly

“functions to provide and protect personal autonomy, emotional release, self-evaluation and limited and personal communication,” has been lost in the emphasis on data control in security development discourse (Lyon 2007, p.174)

²⁷ A risk of a narrow definition of privacy is overreliance on encryption standards to ensure future privacy. State-of-the-art encryption standards may be trivial to break with future advances in computing, particularly in the field of quantum cryptography (Wood 2011). If privacy continues to be narrowly equated with security, we risk viewing potentially breakable technologies as sufficiently guaranteeing the privacy of users, while simultaneously ignoring context-specific privacy expectations (cf. Nissenbaum 2004).

benign personal health data will affect future data privacy, particularly regarding the types of relationships identified between seemingly unrelated pieces of data by custodians.

The implications of long-term storage of PHM data can be conceived of as a problem of context-specific norms of privacy. Revealing the same piece of information has different implications when transferred from its original context of collection/use (cf. Walzer 1983), affected by the identity of the person asking for it, the amount of time it will be held for, and the amount that the person will learn about the user from using the data for a specific purpose (Nissenbaum 2004; Giannetsos et al. 2011). Relationships are central to defining norms of privacy; privacy enables individuals to maintain different relationships with different people (Schoeman 1984) by controlling the information shared, or personal, physical and informational access given to others. With this said, relationships do not identify a piece of information or subject as 'private' as such, but rather define the private areas for which information can be requested (Schoeman 1984, p.411). Areas deemed private are determined by context-specific norms defined by the user; relationships may then be built around such norms. Relationships exist between patients, health professionals and medical paying organisations, with norms of privacy defined in part by the social role played by each actor. These context-specific norms dictate appropriate uses of data which may require revision as the type, quality and quantity of data made available to health professionals changes as a result of PHM. The influx of PHM data thus creates opportunities for violating context-specific expectations of privacy.

User-end privacy policies, embedded in PHM security architecture, could allow users to pre-define expectations of the temporal limitations of data storage, defining for example that personal health data must be deleted after a certain period of time or the completion of a specific project or piece of research.²⁸ The importance of empowering users in this way increases in the face of increasingly sophisticated data mining capable of identifying relationships between seemingly unrelated pieces of data, creating lucrative opportunities for data custodians (Friedewald et al. 2007; Pentland 2009). The potential of data mining increases with the size and granularity of the available data set (Cios & William Moore 2002), providing motivation to retain data for a longer period of time, and use it for purposes

²⁸ A robust ethical review process prior to secondary access to user data could also, in principle, provide a safeguard.

unforeseen at the time of consent. Existing and future protection mechanisms may fail to protect users from undesirable or harmful secondary uses of PHM data (see: Section 3.3.3.2).

3.3.4.1.2 Implications of Myopia on User Awareness

The limitations in development discourse ignores intrusions by third parties into the ‘private’ lives of users unrelated to data dissemination, comprehensible only in terms of personal privacy. Data sharing is at the heart of such disturbances, yet describing the normative character of these violations in purely informational terms misses the disturbing aspect of the intrusion—it is the fact that data is being collected or shared, rather than the content of the data, which is seen as problematic. In other words, PHM systems disturb users through the introduction of third parties into their private spaces and decisions. This aspect of PHM, which can be described in terms of psychological obtrusiveness (cf. Hensel et al. 2006), has not yet received the attention it deserves in the literature, perhaps because its solution does not lie (only) in ‘designing for security’.

The importance of correcting this deficiency in the discourse also lies in the great potential for PHM to violate privacy expectations of users in collecting and handling extremely sensitive personal data. PHM gathers data about health, often within the confines of the home (Rashid et al. 2007). Systems are being implemented to monitor these sensitive domains, yet it is doubtful that users understand the systems’ potential, in terms of violations of privacy and data mining (Beaudin et al. 2006a). Data can be collected and presented in potentially distressing or revealing formats, connections can be identified between seemingly unrelated pieces of information, and a range of unforeseeable secondary uses of increasingly rich longitudinal data sets are possible. Users may assume that developers and data custodians have ‘protected them’ from unanticipated consequences through appropriate privacy policies (Rashid et al. 2007), creating a space in which privacy violations can occur beyond the awareness of the user.

This situation raises a philosophical question regarding whether a user must ‘care about’ their privacy for violations of privacy to occur. ‘Passively’ violating the privacy of an unaware or uncaring user may be just as problematic as ‘active’ violations. A risk exists that a lack of concern for privacy among users could justify further violations of privacy, when the lack of concern may be a product of ignorance of the potential value and (mis)uses of seemingly benign data (Beaudin et al. 2006a; Percival & Hanson 2006; Steele et al. 2009; Remmers 2010;

McLean 2011). Privacy protecting mechanisms, such as user-end privacy policies, are insufficient to protect the privacy of users who are unaware of the potential uses of PHM data (cf. Beaudin et al. 2006a; van Hoof et al. 2007, p.160). Without such knowledge, users lack a rational basis on which their expectations of privacy can be balanced with the technical potential of a system and the potential uses of the data it collects. It should therefore not be concluded that a lack of concern for privacy lessens the value of privacy protecting design and mechanisms, especially while the pervasive potential of PHM data mining remains unclear.²⁹

3.3.5 Medicalisation and Institutional Empowerment

Treatment of medicalisation in the discourse was limited to changes to experiences of the home, and the potential for 'health obsession' due to physiological data being fed back to patients in real time. The visibility of the device may also change the user's experience of identity (see: Section 3.2.5), for example by implying the existence of behaviour expectations stemming from clinicians, family members or members of the public. These expectations can be compared to behavioural expectations for 'disabled' individuals, for example the expectation that a person in a wheel chair will not stand up and walk, or at least lack the ability to do so as implied by usage of the chair. This effect with regard to PHM can be described as the 'medicalisation' of the user's identity.

Medicalisation also changes the meaning of the home, which was acknowledged in the discourse, although the underlying character of the home which is changed, or how the home comes to have meaning attached to it by inhabitants, was rarely explained (e.g. Courtney et al. 2008). This shortcoming confounds understanding how the introduction of monitoring changes experiences with the home in which meaning is developed. According to a western definition, the home is not merely a living space but somewhere with personal meaning, centred on identity, safety and privacy (Williams 2002, p.142), in which the individual is free to act autonomously or control his life "sheltered from the intrusions of public life" (Tamm 1999, p.50), albeit subject to legal intrusions by public officials such as the police in defined and limited circumstances. One way to describe the home is as the "place of greatest personal significance in one's life" where a "sense of belonging and purpose" is developed. The sense of belonging, comfort and familiarity help give meaning to life, and contribute to personal projects and the formation of identity (Williams 2002, p.145). Privacy and identity are

²⁹ For an explanation of how this conclusion suggests a certain theoretical conception of privacy as 'user expectations', and the implications of this approach to privacy for the moral obligations of developers and service providers, see Appendix 3.

simultaneously formed and protected within the home as a safe and comfortable place (Courtney et al. 2008, pp.196–7), where the inhabitant can ‘be himself’ away from outside attention.

The meaning of the home can be changed by the introduction of professional health and care provisions (Courtney et al. 2008, pp.196–7). The effects of PHM on the meaning of the home can be compared with the effects of professional carers entering the home, which can limit the privacy and behavioural freedom of inhabitants due to the intrusion of strangers throughout the day (Tamm 1999, p.49). In comparison, PHM changes the home into a place open to medical institutional scrutiny when continuous monitoring is present—effects are not limited only to the times of day when carers are present. When professional care enters the home, “the home ceases to be an existential centre for the individual and is turned into something between a home and an institution” (Tamm 1999, p.54). PHM can be compared in this sense with hospital monitoring technologies, meaning it creates the possibility for happenings in the home to be shared remotely with health professionals. The home can be conceived as a ‘virtual hospital’, meaning monitoring allows for health professionals and medical institutions to influence the patient through feedback mechanisms (cf. Bohn et al. 2005; Bowes et al. 2011). To this end PHM extends the influence of institutions to spaces previously limited to home visits from clinicians, nurses and professional carers.

This shift in relationships between patients, clinicians and institutions in which the power to monitor and influence patients is extended beyond the walls of hospitals and face-to-face interactions, was not seen in the discourse (see: Section 3.2.9). This situation is problematic, but not because the extension of institutional influence is fundamentally undesirable; for example, it may reduce the need for strangers to enter the home for care, which could be desirable for patients and families seeking to protect the personal space of the home from physical intrusions (e.g. Tamm 1999, p.52). Rather, in providing a new channel for medical influence to enter or ‘medicalise’ the lives and homes of patients, PHM necessitates a new understanding of medical encounters (cf. Emanuel & Emanuel 1992; Heritage et al. 2006); the introduction of remote monitoring necessitates re-visiting how moral obligations or duties which ground medical encounters (e.g. (General Medical Council 2013) can be met when monitoring is used, and the accompanying ‘ethical burdens’ shouldered by patients in allowing monitoring into their lives.

3.3.6 Conclusions

As with any literature review, it cannot be claimed that every example of relevant research was found in this review. With that said, the review occurred over a period of three years, was updated on multiple occasions, and included extensive hand searching of citations found in sources during the database searches. Furthermore, the search query incorporated as many synonymous terms for PHM as found in the literature, meaning that even though the term is not commonly used in the discourse, this feature would not undermine the results of the search. Even if further sources are found, additional analysis would not undermine the critical analysis of moral deliberation, protection mechanisms and the need to address all types of user and systems in the discourse. Beyond the empirical identification of gaps, the criticisms in the discussion are not empirically falsifiable, meaning the mere existence of sources with similar or conflicting claims would not undermine the reasons used to support the conclusions reached in the discussion. Further review may, however, reveal additional gaps in knowledge, or demonstrate that the identified gaps have already been addressed elsewhere.

The quantity of reviewed literature (118) would suggest a large and vibrant discourse of implications of PHM exists in terms of ethics and privacy. However, a relatively small segment of the reviewed literature featured an in-depth³⁰ discussion with reference to relevant background ethical and social theories and concepts (cf. Courtney et al. 2007; Courtney 2008; Kenner 2008; Demiris 2009; Demiris & Hensel 2009; Remmers 2010; van Hoof et al. 2011; McLean 2011; Palm 2011; Rhode 2011; Nordgren 2012; Sorell & Draper 2012). Of this segment, even fewer sources consider PHM as an emerging technology³¹ with unique ethical implications for the future (cf. Brey 2005; Dorsten et al. 2009; Palm 2011; Sorell & Draper 2012). Although several themes were identified in the literature, many studies gave ethical

³⁰ For a discussion to be 'in-depth', it must (at a minimum) mention the theoretical underpinnings of its arguments and explore the (context-specific) meaning of the ethical concepts employed, such as privacy and autonomy. Ideally, studies would also include empirically grounded analysis of the moral beliefs of (potential) users of PHM, and specification of ethical concepts through dialogue, although limitations on the number of individuals currently using PHM (Courtney, Demiris, and Hensel 2007) as well as methodological difficulties associated with the ethical analysis of future states serve as barriers (Brey 2011).

³¹ This finding could possibly be explained by the necessary usage of synonymous terms in the search query, which would refer to existing types of technologies. Given the lack of common terminology in the field (as revealed in the reviewed literature), the legitimacy of this explanation must remain in doubt. However, terms such as "personal health monitoring," "ambient intelligence," "ubiquitous computing," and "somatic surveillance" are typically used to refer to technologies either in developmental stages or predicted to emerge in the near future, so there is reason to believe that the alleged lack of future-oriented discussion of PHM is legitimate.

theory and concepts little more than cursory treatment because the explicit goal was often not ethical analysis (cf. Welsh et al. 2003; Coughlin et al. 2007; Fugger et al. 2007; Lauriks et al. 2007; Gammon et al. 2009; Stowe & Harding 2010; Tiwari et al. 2010; Ziefle & Röcker 2010; Frisardi & Imbimbo 2011; van Hoof et al. 2011; Kovach et al. 2011; Rigaud et al. 2011). In particular, privacy is discussed frequently, but superficially. This gap in knowledge is important because the development, deployment and discussion of the ethical aspects of PHM are still in early stages. To ensure PHM is deployed in an equitable and beneficial manner, further research into some of the gaps identified here is required prior to widespread deployment.

The lack of in-depth analysis and the use of vague or undefined ethical concepts reflect that theoretical understanding of the moral potential of PHM as a technology is still in early stages. Similar to the ‘policy vacuums’ created by innovations in ICT (Moor 1985), a ‘conceptual vacuum’ appears to exist by which the functions of PHM and its implications for social life are not yet understood within a rational theoretical framework. To begin to address this gap, it is necessary to take a closer look at how the various themes of seen in the discourse can begin to fit together to explain the moral potential of PHM as an emerging technology.

3.4 Conceptual Framework to Link Discourse Themes³²

Although the discourse contains many weaknesses and gaps as identified in the previous section, it provides valuable insight into the moral potential of PHM. To fill the conceptual vacuum created by PHM and make sense of the literature, a conceptual framework is required which can reveal common ground or connections between the disparate themes.

Medicalisation hints at a broader conceptual framework, which could be based on Habermas’ notion of the system/lifeworld divide (Habermas 1984; Habermas 1985), to connect the various ethical implications seen in the discourse.

3.4.1 The System Lifeworld Perspective

The use of PHM, in which data about a patient’s condition is transmitted to a central point, provides benefits for both the hospital and the patient. The patient may gain peace of mind by knowing his safety is increased through constant monitoring, enabling advice on when an intervention is necessary and continuity in contact with clinical staff. As a result hospitals may be able to release beds, to work more efficiently and to reduce unnecessary admissions (cf.

³² The discussion of the system/lifeworld perspective and colonisation of the lifeworld is taken in part from a paper co-authored with Neil McBride, Ben Fairweather and Mark Shaw, which is currently under review for publication by the International Journal of Technoethics. See: Appendix A18.1.

Henderson et al. 2013). A delicate balance must be struck between two domains of communication distinguished by the concerns of the patient and the concerns of medicine or medical institutions, which can be characterised in Habermas terms as the lifeworld and the system, respectively (cf. Habermas 1984; Habermas 1985). The ethical themes found in the discourse—privacy, autonomy, visibility, stigma and identity, social isolation, care delivery, safety and medicalisation—are all influenced by the nature of the system/lifeworld relationship.

The lifeworld of the patient concerns the personal domain of the user, or the values, traditions, culture, accepted ways of behaving and being which are developed within families and cultures and expressed within the home and through cultural and social norms (Habermas 1984; Habermas 1985; Edgar 2002, p.89). A person's lifeworld is lived-out within personal environments such as the home and connected communities, in which a sense of belonging and safety is sought. The lifeworld is concerned with quality of life and qualitative communication, and is formed and maintained through social communication in which relationships with communities are established (Edgar 2002, p.89), often with an emphasis on the private and the hidden. The lifeworld may be expressed in the home in terms of layout, the arrangement of objects, and the meanings given to the space relating to identity, safety and privacy (cf. Williams 2002, p.142). However, the lifeworld should not be confused or equated with the home or traditionally private spaces—it exists in these places as well as the relationships between members of a community, and is lived out by the individual in daily life.

Rather than a physical space, the lifeworld exists in domains in which consensual communicative action is possible based upon mutual understanding, established through shared cultural understanding or norms, institutional and familial structures. It encompasses a certain set of competencies, practices and attitudes establishing mutual understanding necessary for communicative action (Habermas 1984, chap.6). At the heart of the lifeworld is a concern about who the user is, and who they are as part of a community. In this sense PHM can exist within and change the user's lifeworld wherever PHM is used—in the home, on the body, in work spaces or vehicles, or any other potential context of use.

In contrast, the system is not concerned with the personal, social, private or informal aspects of life, but rather with the domain of institutions, power and economic goals, the public sphere and the control of resources (Habermas 1975). The system can be said to exist wherever it is

understood that some actors in communication will pursue strategic action, often for shared purposes or mutual benefit (Habermas 1984, chap.6): medical practice, in which communication is structured in a certain way to facilitate clinicians receiving required information from patients in an efficient manner (Barry et al. 2001), is one such example of how the system can influence communication. System discourses concern concepts such as cost-benefit analyses and quantitative communication. The system requires predictability and control hence there may be an emphasis on rules, structure and organisation. Simplification is necessary not only for actors in the system to pursue external goods (e.g. efficiency) and maintain the social practice, but also to allow for stakeholders to understand and participate in these practices (Edgar 2002, p.19). Acting on the basis of predicted actions allows for increasingly complex social interactions to be controlled by the system (Edgar 2002, p.17), when the system is understood as situations or contexts in which communicative action is not necessary or possible.

3.4.1.1 Colonisation of the Lifeworld

The need for simplification, prediction and control to achieve external aims through strategic action is not itself a problematic feature of the system's relationship to the lifeworld; however, treating actors as deterministic entities rather than socially embodied individuals capable of meaningful communicative action means values and actions of the lifeworld are increasingly restricted and limited to system concerns (Habermas 1985). The 'colonisation of the lifeworld' occurs when the system seeks to exert influence on the lifeworld by controlling or monitoring it, limiting opportunities for rational discourse and eroding meaningful communication through strategic action (Habermas 1984; Habermas 1985). Examples of colonisation can be seen in the advent of personalised advertisements which aim to influence user behaviour, crafted according to 'cookies' storing information about internet usage on home computers (Truong et al. 2010), or when behaviour in the home concerning child discipline becomes a subject of legislation (Barnett 2008). The colonisation of the lifeworld by the system may pit social and personal life against institutional and legislative life.

Through colonisation social interactions become increasingly instrumental or guided by anticipated reactions (Edgar 2002, p.9), reducing the need for communication or shared meaning. Complex social processes involve too many stakeholders and resources to allow for meaningful communication between actors at all times, meaning stakeholders must be treated as 'means to an end' (cf. Kant 1998) at times (Edgar 2002, p.18). Meaningful actions are

treated as “mere behaviour,” meaning the system acts strategically rather than communicatively towards the lifeworld (Edgar 2002, p.18), seeking to manipulate actors towards desired ends rather than establishing shared meaning (Jones 2001, p.70; Scambler & Britten 2001, p.52; Edgar 2002, p.23). The freedom to engage in meaningful communicative action, central to the maintenance and meaning of the lifeworld (Habermas 1985), is eroded as the system’s attempts at complex social projects necessitates “impoverished forms of interaction” based on predicted patterns of action (Edgar 2002, pp.90–1). The possibility of communicative action (see: Section 7.3.2), understood as a deliberative process entered into when communication breaks down and validity claims are questioned (Habermas 1985; Edgar 2002, p.42), is eroded through systemic strategic action seen in colonisation.

Colonisation in this sense can change the ‘background’ components through which mutual understanding is achieved in the lifeworld (Habermas 1984, chap.6). Colonisation can be said to occur when the distinction between domains or situations in which the system and lifeworld exist begin to blur; or as it becomes less clear when and by whom the rules of communication are relaxed to facilitate action (Habermas 1985). When the system is defined by such situations (e.g. Habermas 1984, chap.6), the lifeworld is colonised by the system whenever an actor undertakes strategic action that is not obvious to other participants in communication. In this way the lifeworld can come to be characterised by ‘background’ elements, such as value systems, derived from the concerns of the system which enter the lifeworld when standards of communication are relaxed. Colonisation is the process by which the system’s concerns related to external goods achievable through strategic action come to replace lifeworld concerns for communicative action and mutual understanding (Habermas 1985). Colonisation can thus be enacted by actors acting strategically, or expressing themselves in terms of the system’s values or concerns (Habermas 1985; Scambler & Britten 2001). For example, when patients come to view themselves or express concerns through medical terminology intended to facilitate medical care in the pursuit of external goods (e.g. health, efficiency), colonisation of the patient’s lifeworld has occurred (e.g. Scambler & Britten 2001); the concerns of the system have changed how patients express themselves in communication outside of system domains, such as the clinical encounters.

The alteration of goods/values internal to specific lifeworlds is accomplished through the erosion of “communicative skills that are grounded in, and that serve to maintain, the lifeworld” through “the instrumentalism inherent in systematic activity” (Edgar 2002, p.21)

undertaken in coordination and sustenance of complex social processes. In adopting the language and concerns of medicine, understood as a system domain concerned with the complex social project of maintaining the health of individuals in a society, the lifeworld of the patient is colonised (Scambler & Britten 2001); beliefs about health are understood in terms of the system's values (e.g. external goods), and expressed through the language used by the system beyond its current boundaries.

However, it is not just a case of the system invading the lifeworld like colonial masters entering a tribal society. Many systems concerned with quantities within the medical environment—processes, bookings, money and boards of directors—understood as components of the system, exist to serve and are legitimised by the lifeworld as they help control social processes too complex for communicative action (cf. Habermas 1975; Edgar 2002, p.90). In exploring the system/lifeworld relationship, influence in both directions should be considered, although the power balance may be in favour of the system's invasion of the lifeworld.

3.4.1.2 Colonisation and Relationships

Colonisation cannot occur without a relationship between the system and the lifeworld (Habermas 1975). At a practical level the relationship is seen between actors expressing concerns of the system and the lifeworld respectively, e.g. professionals and laypersons, politicians and citizens, doctors and patients. These relationships are the channel through which colonisation occurs. In medicine this relationship does not exist between the patient and a lone institution, but is instead an amalgamation of the various (in)direct relationships the patient has with medical institutions and their representatives. PHM will act as a mediator in these relationships, potentially opening the patient's lifeworld to colonisation. It is therefore necessary to give attention to how PHM will change interactions between patients, medical personnel and institutions, and whether these changes are ethically problematic.

3.4.1.3 PHM as Mediator

Within this perspective the role of PHM can be described as another communicative mediator of discourse between the system, the concerns of which are expressed by medical institutions (e.g. hospitals, paying organisations) and practitioners bound by system norms (for example, through professional associations or codes of conduct), and the lifeworld of the patient. PHM bridges the communicative space between the lifeworld and the wider concerns of society enshrined in the system. PHM has the potential to enable the colonisation of the lifeworld, as

the patient's daily life becomes an extension of the hospital or GP office and the concerns of the institution shape the background components of the lifeworld which enable communicative action, or attitudes, values and behaviours of the patient. PHM enables the quantisation of health parameters and behaviours outside of system domains, such as clinical encounters and hospital stays, such that the needs of the system become the concerns of the lifeworld, blurring the distinction between system and lifeworld domains. If this view of PHM is accurate, the technology enables systemic strategic action through which the patient's lifeworld is increasingly assessed against system values, for example by emphasising quantifiable monitoring data in clinical decision-making or care commissioning, or encouraging monitoring as a replacement/supplement to face-to-face care for efficiency's sake.

An example of how PHM introduces system concerns may help clarify the technology's role in colonisation. Feedback can be provided to the patient on the basis of PHM data concerning changes in physiological parameters. A connection may be established between behaviour and health. In both cases system values or concerns are introduced into the patient's lifeworld, lived out in the home and connected communities outside of the system's domain, influencing how the patient understands his behaviour and health in the lifeworld. When a connection is established between activities in the lifeworld and medical concerns, a link has been made between system and lifeworld through which colonisation can occur. To be clear, patients undeniably have an interest in their health and well-being which is part of their lifeworld; system concerns are only introduced when health is understood as an aspect of medicine, expressed through clinical language or parameters, as would be the case with PHM which enables monitoring of physiological parameters and behaviours that can be linked back to physiology. Medical concerns and language belong to the system so long as medicine is conceived of as a complex social project seeking to address the health of individuals in a society, necessitating institutions and social systems to achieve its goals (see: Section 4.3.2).

While this example does not exhaust potential modes of colonisation via future uses of PHM, it does show that the technological capacities of PHM can blur the boundary between system and lifeworld, as communicative action in the lifeworld comes to be replaced by strategic action and the concerns of the system. PHM can increase personal communication, and develop safety, peace of mind and security such that the lifeworld is preserved and developed. However, PHM can also restrict the lifeworld, impinging the system's concerns on the lifeworld such that restrictions are placed or information demanded in order to maintain institutional

structures or clinical expectations. The capacity for PHM to impede communicative action in the lifeworld extends to relationships with clinicians if PHM contributes to a greater focus in clinical encounters on 'objective' PHM data representing the patient's physiological health and behaviours in medical terms, precluding opportunities for discussing health in the "voice of the lifeworld" (Barry et al. 2001). The possibility for communicative action between clinicians and patients is reduced in this way because external goods, such as the availability of treatments, influence clinical encounters and may change how the patient self-identifies (e.g. "I am a hypertension patient") or understands his health (e.g. increasingly in medical terms).

The concerns with simplifying and restricting discourse through colonisation of the lifeworld are also relevant to the influence of medical institutions on clinicians and clinical practice. Communication between clinicians and institutions may also be distorted by PHM, for instance if institutions commission or encourage reliance on PHM and its data, which are seen to provide an 'objective' account of the patient's health or 'efficient' method of clinical care. The 'lifeworld' of clinicians (if such a thing exists), or at least the relationships between clinicians and institutions, may therefore increasingly focus on the concerns of medicine as a system domain or complex social project.

By sending data about a patient to a central location, PHM opens the patient's lifeworld to broader system scrutiny. The placement of a monitoring system in a patient's lifeworld means the patient's physiology and behaviours are increasingly amenable to remote analysis, feedback and decision-making, each of which has implications for the user's subsequent care and identity. Colonisation may be understood as PHM exerting influence over the behaviours and values of the user, changing the values against which the user judges his actions to those represented by the PHM application, seen for example in analysis algorithms (e.g. equating a physiological reading with a problem) or feedback (cf. Molewijk et al. 2003).

PHM allows the patient's lifeworld to be evaluated at a distance, and his future medical choices to be limited by remote decision-making outside clinical encounters (cf. Lyon 2003). The ability of the patient to give meaning to his life, to define and pursue personal projects, to self-identify in a way matching the values of his lifeworld, are thus eroded by the systemic colonisation of the lifeworld through which behaviours and values subtly adapt to the rules and expectations of the system conducive to its continued maintenance (Habermas 1984, pp.346–8). Colonisation need not be forced, or actively pursued by an institution with an

agenda for controlling the behaviours of patients, or governing private behaviours according to institutional values. Rather, colonisation can be a subtle by-product of using PHM, introduced as much through the institution's intervention recommendations as by the patient's independently formed perceptions of PHM as surveillance, or a 'portal' through which their behaviours and health parameters can be seen by the outside world. Indeed, the perception of an institutional agenda can affect how PHM is perceived by the user (cf. Sorell & Draper 2012, p.40), with implications for the degree of self-discipline and behaviour modification exercised.

PHM has the potential to act both as the repressive father, dictating behaviour and routine and demanding information for his own purposes, or the supportive mother offering both reassuring feedback and a sense of safety stemming from constant medical 'attention' (cf. Essén 2008). As such ethical implications are both produced by and flow through PHM as a mediator. PHM is a conduit for the flow of ethical concerns between the system and the lifeworld which inevitably alters the potency of such concerns and the ability of the user to manage them. Each of the ethical themes identified in the literature review may be interpreted in terms of effects of PHM on the relationship between system and lifeworld.

3.4.1.4 Ethical Themes as Colonisation

The themes identified in the discourse (see: Section 3.2) can be connected within the colonisation framework. PHM may compromise privacy because it provides the system with access to information about activities and behaviour outside of the GPs office or hospital, for example through monitoring via sensors in the home or a device worn by the user, or through data entered by the patient into an Internet-connected interface, as has been seen in patients with chronic obstructive pulmonary disease (COPD) (e.g. De Toledo et al. 2006; Ure et al. 2012). Similar data may be provided by PHM to the user's lifeworld, for example when data is shared with family members or acquaintances that the user would prefer not have access to the data, such as homebound elderly individuals not wanting to share information about risk taking with family members (e.g. Percival & Hanson 2006; Remmers 2010). Data may potentially be misused and access to the data represents an invasion of privacy by the system. Pervasive categorisation and evaluation of patients as data sets, rather than as socially embodied persons (cf. Lyon 2003; Monahan & Wall 2007; Light 2010), becomes possible, which may lead to a greater reliance on 'objective' PHM data in clinical encounters (Monahan

& Wall 2007, p.168). However, the mere use of the PHM may enable a patient to be based at home rather than in a hospital where privacy will be much more restricted.

While autonomy may be promoted by the release of the patient from the confines of hospitalisation, PHM also allows the system to invade the lifeworld and exert control through the quantisation and regulation of behaviour in personal environments. Rituals and routines in the home become the concern of the system, as they become visible, and the patient is encouraged to concern himself with system priorities in the pursuit of better health or medical care. Behaviours may become more controllable as they are measured alongside physiological characteristics and interpreted within medical paradigms, or as parameters of health. These measures, when provided to the system may result in intervention which regulates the behaviour of the user according to strategies and protocols legitimised by the system. It is in this sense that PHM is a surveillance technology—it allows for the evaluation of the user at a distance as a quantified set of measurements, removed from the socially embodied person they represent. In this sense contextual awareness, or information about the factors in the patient's life affecting measurements such as the death of a loved one, can be lost from medical relationships and clinical encounters mediated by PHM data (e.g. Kenner 2008, p.264).

PHM may also affect the user's identity and behavioural patterns derived from the lifeworld. Behavioural patterns must be adapted to meet the requirement of the PHM application, whether that is in routines of monitoring by recording and transmitting physiological and behaviour data, or by routine of intervention, where therapies are conducted in response to the output of the PHM application. Interpretation of the meaning of numbers generated by PHM is most likely to be a system interpretation based on accepted protocol, research and clinical practice (cf. Molewijk et al. 2003). The underlying values of interpretation affect the lifeworld in making judgements about physiological state and behaviour as to whether it is 'good' or 'bad', thus restricting the future opportunities of the user (cf. Lyon 2003). The 'expectations' built into a system, or the patterns which define 'normal' and 'abnormal' behaviour, become very important in this context; developers and medical institutions administering PHM passively control the behaviours of users by defining physiological and behavioural norms. Such norms may effectively be ethical judgements, such that the system is imposing moral boundaries on the lifeworld.

While reducing the obtrusiveness of PHM might help minimise the effects on a user's identity and autonomy, expressed through behaviours, the system still affects the lifeworld through remote evaluation, feedback and interventions. Those interventions are determined by the system, based on clinical information and accepted treatment protocols and on the needs of the system which may concern economic justification of service provision or funding (Froggatt et al. 2011).

The way in which PHM acts as a conduit between the lifeworld and the system may support medicalisation in which the power imbalance between system and lifeworld, particularly amplified by the patient's dependency on the system, results in an invasion of the lifeworld in terms which may be described as medicalisation. The system's concerns are channelled through PHM as a mediator in medical relationships, affecting the character of the lifeworld lived out in the home with relationships between patients, family and members of the community. Positively, connecting the system and the lifeworld through PHM may reduce isolation by legitimising contact with healthcare personnel and care workers (Gale & Sultan 2013). However, social isolation may also prevail if PHM gives the impression of 'caring for' the user in place of a human carer.

Interpreting delivery of care through the lens of system/lifeworld raises further issues. System concerns for control, regulation and economic management may not only be exerted on the patient as the user of PHM, but also on carers and clinicians. It might be speculated that economic demands to optimise the use of paid-for care may result not only in the reduction of contact hours but also in the management and control of care giver activities through the proxy of PHM showing how metrics change when the carer is present. Clinicians may be encouraged to move increasingly towards remote monitoring and self-care of chronic illnesses to better prioritise their time. The system's agenda for safety can also colonise the user's lifeworld with PHM acting as a conduit, by introducing regulations and standards appropriate for institutions but restrictive in the context of the home environment, with the knock-on effect of changing the private behaviours of patients to meet institutional expectations. Rhetoric concerning technological need may increasingly be used by patients and institutions alike to justify further monitoring, even though the need is created more by the system's requirement for efficiency or revenue than the patient's clinical or personal needs.

3.4.2 Linkage between Ethical Themes

The themes identified in this review do not constitute a catalogue of stand-alone concerns but are linked together in a network of interactions. Using the technique of cognitive mapping of the issues discovered around the themes (Eden 1988; Eden 1992), a cognitive map (Figure 3.2) has been constructed.

The map illustrates the web of influences between the ethical themes identified in the discourse from the perspective of the patient as user of PHM. The links between issues identify positive (+) and negative (-) relationships between themes and concepts seen in the literature (see: Section 3.2), wherein positive relationships indicate a concept 'increases' or 'contributes to' the connected concept, and negative relationships indicate a concept 'reduces' or 'detracts from' the connected concept. Two particular phenomena can be identified. First, cascades of links such that an ethical issue may have an effect further down the line, the link for which may not be obvious. For example, PHM reliance, which is influenced by perceived need, may increase surveillance, which may increase the power exercised by carers, clinicians or institutions and reduces patient autonomy and privacy. This type of map may enable researchers and practitioners to identify initial concerns, which through a cascade of ethical themes may exert unexpected influence on key ethical concerns. This is not to say the links identify causal connections, according to which positive and negative relationships exist acontextually between the identified concepts; for example, the link between obtrusiveness and PHM subversion does not mean a user will always subvert or disable monitoring systems perceived as obtrusive. Rather, links identify possible connections between ethical concepts linked to PHM in the reviewed literature, indicating potential implications of using or designing PHM to act in particular ways in particular contexts. In other words, these are examples of issues that may arise, rather than predictions about what will actually happen once the technology is in the hands of doctors and patients.

In some cases the links resemble the ethical tradeoffs previously described (see: Section 3.3.2); for example, perceived need, acting as a sort of reliance on PHM, reduces autonomy and increases medicalisation. In practice, a proper evaluation of safety needs which makes a realistic assessment of actual risks, and considers the patient's medical and social needs above those of institution and carers, may reduce the perceived need for PHM and hence protect autonomy and privacy.

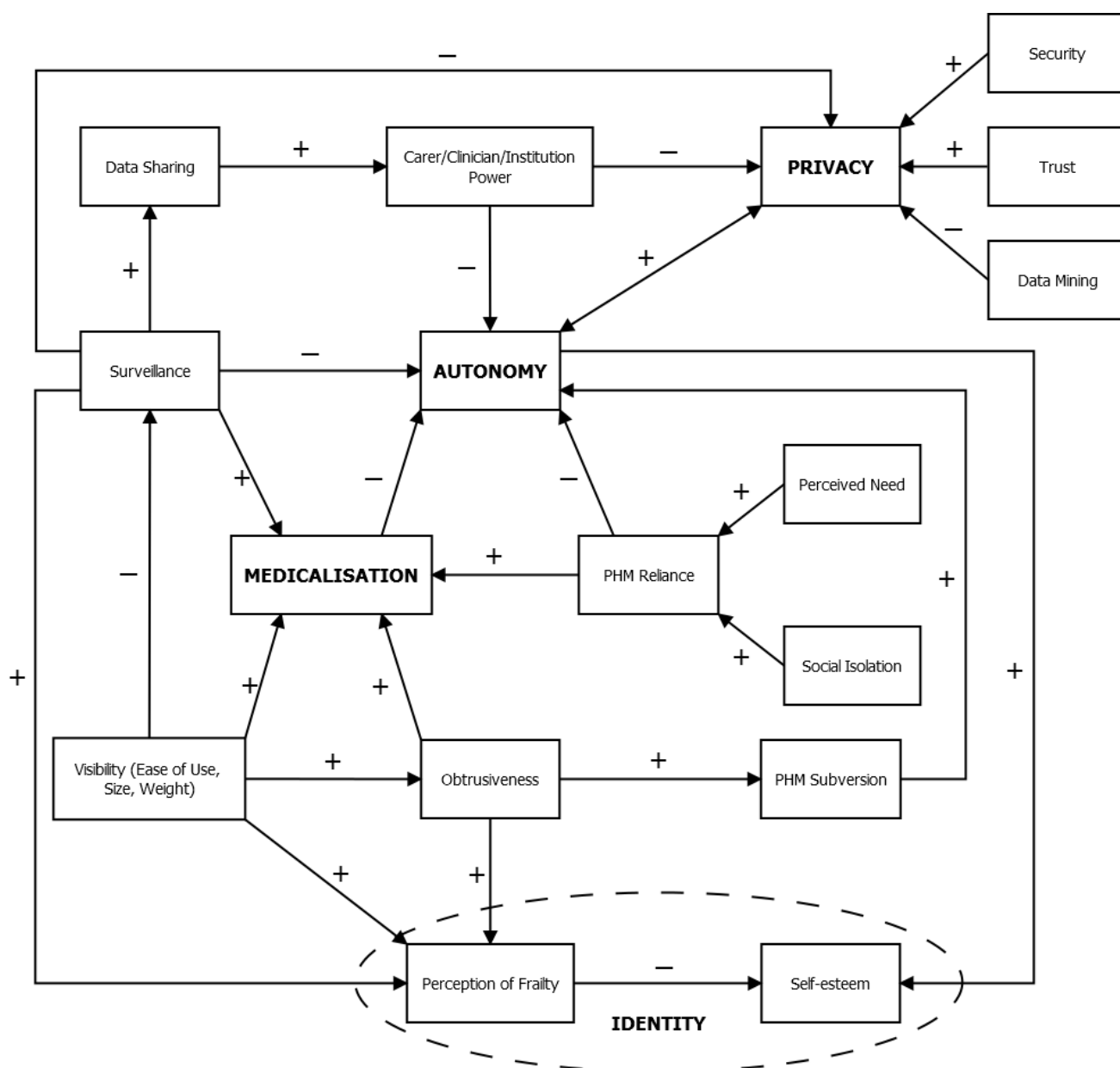


Figure 3.2 - Cognitive Map of Linkages between Ethical Themes from the Perspective of the User

Second, certain ethical issues are dominant and the target of other ethical influences.

Autonomy, privacy, medicalisation and identity are highly interconnected issues, suggesting future research may need to focus on implications of PHM in these terms.³³ At a theoretical level, each of these concepts can be viewed through the colonisation framework, which puts ethical implications in terms of the effects of PHM as a mediator in medical relationships

³³ With that said, the dominance of privacy in the discourse suggests that the other themes take precedence in future research, besides the need to address the weaknesses identified in privacy discourse (see: Section 3.3.4).

through which the system and lifeworld meet. However, this account of colonisation lacks insight into how colonisation is actually experienced by stakeholders. It would seem, then, that the theoretical account of PHM as a tool of colonisation can be further developed through research into specific contexts of use, in which PHM enables colonisation. This type of research benefits from the cognitive map which explains how concepts and characteristics of PHM are linked or cascade within the colonisation framework.

3.5 Colonisation of the Lifeworld as a Framework for Further Research

The need for further consideration of the colonising effects of PHM suggests that understanding the relationships between patients, medical practitioners and institutions can help clarify the 'moral potential' of the technology. Ideally, critical discourse between the patient and the professional concerning implementation of PHM, the interpretation of data and the behavioural and clinical interventions resulting from the PHM should result in greater understanding of how the patient's lifeworld can be supported, and colonisation of that lifeworld by the system controlled. Hence PHM is a subject for dialogue which will raise issues about care, independence, progression and treatment of a disease which extend beyond the technical confines of PHM. A conceptual framework built around medical relationships can facilitate dialogue between these parties aimed at preventing undesirable colonisation of the patient's lifeworld. Studies are needed which examine the influence of PHM as a mediator in the various medical relationships through which colonisation occurs, so as to provide a referential framework for future dialogue through which potential problems may be identified and mitigated.

Limiting study to patient-clinician relationships is, however, not sufficient to understand the broader colonising potential of PHM. In moving care away from the face-to-face model and more towards remote and self-care, the introduction of PHM will undoubtedly have implications for the practice of medicine. Habermas spoke of the colonisation of lifeworlds, or private domains and communities inhabited by individuals (see: Section 3.4.1). Medicine does not have a 'lifeworld' as such; however, if conceived of as a practice unified by a set of accepted norms, principles or duties, PHM can be said to contribute to the colonisation of the practice of medicine with institutional values. It is appropriate to conceptualise medicine as such a practice, with internal norms against which 'good' medical activity, or good medical relationships, can be defined (cf. Pellegrino & Thomasma 1993; Pellegrino 2002; MacIntyre

2007). For individuals, autonomy can be inhibited by the introduction of institutional values into the home; similarly, the internal norms of medicine may become increasingly difficult to realise in caring relationships mediated by PHM. Doctors may be restricted by institutional norms of care, or increasingly view patients as amalgamations of parameterised health data.

3.5.1 Research Question

Further research is necessary into the implications of colonisation brought about by PHM mediated medicine from the perspective of not only patients, but medical personnel and institutions as well. Accessing the unique experiences of these stakeholders will hopefully identify and specify examples of colonisation and medicalisation not seen in the discourse. This need for further research into PHM and medical relationships is the source of the main research question addressed by this thesis:

What ethical considerations will arise when PHM is introduced into relationships between patients, clinicians and medical paying organisations?

The proposed outcome of answering this research question is a conceptual framework for analysis of emerging PHM applications (see: Section 1.2.6). A framework should assist in understanding the normative dimensions of a technology, linking together the various uses, technological characteristics and normative implications into a coherent whole (Moor 1985). Such a framework should be useful to individuals and organisations for proactively identifying and addressing ethical issues. As an emerging technology, PHM does not yet have such a framework.

3.6 Conclusions

While implications for patients, medical personnel and (to a limited degree) medical paying organisations were seen in the literature, they were not linked by an underlying framework characterised by PHM enabling colonisation of the patient's lifeworld by concerns of the system. As has been argued above, such a framework can help explain ethical issues created when introducing PHM precludes the possibility for communicative action in the patient's lifeworld, and in communication with clinicians (e.g. Habermas 1984, chap.6). PHM can be conceived of as a mediator in the various relationships between patients, clinicians and institutions that constitute medicine as a practice (see: Section 3.4.1.3). In this role PHM enables the colonisation of the lifeworld of patients and clinicians with institutional values.

A lack of research is evident in PHM ethics discourse into the implications of PHM as a mediator in medical relationships. For patients, a cognitive map of connections between the various issues raised in the literature suggests that further research needs to focus on the effects of medicalisation on autonomy, privacy and identity as monitoring increasingly opens the patient's lifeworld to external scrutiny. For clinicians, the internal goods of medicine (see: Section 4.3.1.1) may be modified or inhibited by working towards a model of care meeting the needs of the system, or more simply away from face-to-face encounters and towards remote monitoring, self-care and informal care of the elderly and dependent (cf. Williams 2002, p.142). The ethical implications of inserting monitors into caring relationships, and the resulting shift in power in relationships between medical institutions, clinicians and patients, is not yet well understood.

This gap in the discourse led to the identification of a third research question focusing on the ethical implications of PHM for medical relationships. To begin to answer this question, a better understanding of the values by which medical practice may be evaluated is needed. The next chapter continues to construct a conceptual framework for PHM, first examining the ends of medicine, connecting them to virtues which provide evaluative standards for ethical analysis. On this conceptual basis ethical analysis of the influence of PHM as a mediator in medical relationships, where PHM is conceived of as a form of medical surveillance, can be undertaken.

4 Chapter 4 – A Conceptual Framework for PHM

4.1 Introduction

To move PHM ethics discourse forward and answer the third research question (see: Section 3.5.1), further research is necessary into PHM as a mediator in medical relationships. This chapter addresses this gap by exploring ethical and social theories relevant to understanding the ethical impact of PHM across different contexts as a form of colonisation, teasing out their implications for a conceptual framework of PHM based on the ends of medicine as a practice, and identifying how they are inadequately applied or absent from current discourse. As a general criticism, much of the discourse fails to follow through the implications of a particular ethical theory, concept or protection mechanism in-depth, working out its logical limitations and nuances when applied to PHM. This type of theoretical analysis, missing from the discourse, is undertaken here concerning theories missing or inadequately applied in current discourse. By relating virtue ethics, theories of surveillance and medicine to colonisation of the lifeworld, a conceptual framework begins to take shape which can explain how PHM may be allowed to change medicine as a practice in an ethically problematic way from the perspective of patients and practitioners alike. This analysis builds upon and adds to the theory of colonisation of the lifeworld as a framework (see: Section 3.4) for understanding the many implications of PHM seen in the discourse.

The conceptual framework is intended to help identify linkages between some of the themes and gaps found in the literature review. Initial linkages have already been identified on the basis of colonisation, as seen in the cognitive map in Chapter 3 (see: Figure 3.2). The framework itself consists of the unique way in which theories of virtue ethics, surveillance, medicine and colonisation of the lifeworld are interconnected and applied to PHM in this chapter. The cognitive map is not part of the framework, but rather a tool which shows how the framework applies to particular ethical themes and concepts when considering the implications of PHM for medical relationships. In practical terms, the links identified in the map are intended to be identified and unpacked within the framework described in this chapter. Following the description of the conceptual framework and consideration of the results of an empirical study involving potential users of PHM, the map will be updated with additional links that can be explained through the framework (see: Section 9.4.1).

4.2 Utilitarian Support for PHM

When PHM is seen as a desirable technology because it is thought to reduce the costs or need for human interaction in healthcare (see: Section 1.1), a certain conception of ‘good’ healthcare is advanced at least implicitly based on utilitarianism. The core concept of utilitarianism in its various forms is that an action is right or good in so far as it maximises utility by producing the greatest benefits for the greatest number (of people, sentient beings, animals), with benefits often understood in terms of happiness and suffering (Mill 2002), or pleasure and pain (Bentham 1948). Assuming that healthcare resources are finite, from a utilitarian perspective PHM tends to be a good technology if it increases the number of people that can be treated without reducing the quality of care. These types of gains are predicted to be necessary in EU countries currently facing a demographic crisis, with resource shortfalls predicted in healthcare (see: Section 1.1). Another way to understand the concern over the effects of shifting demographics on healthcare is that available resources will not be able to meet the assumed (see: Section 1.1 note 1) or predicted growth in demand, meaning either fewer people will be cared for or the quality of care will be reduced. Both outcomes are undesirable from a utilitarian perspective, and can be understood as harming the patients with a legal right to services from such a healthcare system.

In terms of ethical analysis, PHM would be more or less ethically acceptable according to its implications for resource expenditures in healthcare. For any specific patient, if PHM is able to deliver healthcare of the same or better quality compared to current care at lower costs, it is an ethically preferable alternative because the ‘saved’ resources can be directed towards extending or improving care of other patients. This sort of simple utilitarian calculus is a driving factor in strategic support for PHM to lower the costs of healthcare (see: Chapter 1). In current discourse the dominance of utilitarian thought on strategic support for PHM was not questioned, with utilitarian or consequentialist theory rarely mentioned (cf. Berdichevsky & Neuenschwander 1999; McLean 2011). However, limiting ethical analysis to financial considerations is unacceptable, given potential ethical implications which cannot be measured quantitatively in terms of distributing limited resources fairly among patients (see e.g. Sections 3.2.1, 3.2.5, 3.2.9). To prevent ethical harm justified by basic utilitarian calculations, PHM must be proactively assessed with alternative ethical theories which define ‘good’ actions beyond financial considerations.

This is not to suggest utilitarianism is useless in ethical assessment of emerging medical ICT, but rather that its application is too often limited to a basic calculation in which ethical acceptability is linked directly, and only, to financial concerns calculated quantitatively as a measure of happiness. Simplistic calculation does a disservice to complex theories of utility, such as Mill's hierarchy of intellectual, moral and physical pleasures (Mill 2002), or Singer's utilitarianism based on preference satisfaction (Singer 1993). Utilitarianism allows for consideration of non-financial goods grounded in the preferences or capabilities of humans (and animals); implications of data sharing can be assessed in terms of satisfying the preferences of affected stakeholders for privacy or autonomy, for example.

As the practice of medicine changes in the face of emerging technologies, "something of the past is inevitably lost, not always for the worse" (Pellegrino & Thomasma 1993, p.32). This sentiment suggests that the sort of changes faced in adopting PHM in medical care may not be undesirable—after all, if PHM allows for more patients to be cared for adequately compared to existing treatments, its adoption should be recommended on utilitarian terms. However, the thesis explored here is that utilitarianism is an incomplete framework for assessing the potential ethical harms and benefits of PHM because the various implications for stakeholders (see: Chapter 3) cannot and should not be simplified for comparison and weighting in terms of utility, or benefits/harms, pleasure/pain or preference satisfaction. Even if a sophisticated approach to utility such as preference satisfaction could treat various ethical implications as different components of utility, it remains unclear how relative importance of goods should be assessed; for example, does monitoring an additional cohort of patients justify a reduction in face-to-face care? Limiting evaluation of the ethical implications of PHM to the utilitarian terms favoured in strategy (see: Section 5.2), where ethical acceptability is implicitly assessed in terms of patients seen, mortality, length of hospital visits and other temporal or financial measures, is unsatisfactory because it cannot account for implications of PHM beyond utility.

With these problems in mind, what is needed is a theoretical framework which provides a basis for comparing the ethical acceptability of monitoring to existing medical care beyond the limitations of utility—one which helps explain the ends towards which medicine as a practice works. If it can be shown that the model of care created by PHM is somehow deficient in achieving the ends of medicine as a practice beyond quantitative measurements of quality (or utility), then a utilitarian account must be deemed incomplete.

4.3 Virtue Ethics and Medicine as a Moral Practice

Virtue ethics is seen as a way to demonstrate the shortcomings of utility for ethical assessment of PHM. Virtue ethics is capable of explaining how PHM will either inhibit realisation of some of the ends of medicine, according to which patients are cared for as complete socially embodied persons (Haggerty & Ericson 2000; Lyon 2007, p.55), or persons with unique histories, values, needs and expectations of care, and not merely bodies presenting a disorder.

Traditionally, virtue ethics was based on the *telos* of humanity, meaning that virtues are “habitual dispositions” to act in accordance with the ends of human life which define a ‘good’ life (Pellegrino & Thomasma 1993, p.8). An Aristotelian approach to virtue ethics has been the most influential, with a ‘means’ based approach to defining virtues as the mean between two vices (Pellegrino & Thomasma 1993, p.6; Darwall 2003). Modern virtue ethicists (e.g. Darwall 2003; MacIntyre 2007) move beyond Aristotle’s ‘mean’ based account of the virtues, acknowledging that certain virtues such as justice or fidelity to trust cannot have a mean (Pellegrino & Thomasma 1993, p.6). Virtues act as a hermeneutic tool (Edgar 2005, p.166) helping individuals interpret, define and pursue the ‘good’ life.

Virtue ethics is not merely an alternative ethical theory to established positions. Consequentialist and deontological theories make prescriptions between right and wrong *actions*, prescribing how to live a good life through moral conduct. In contrast, virtue ethics is concerned with *character*, not conduct—it prescribes “how we should *be* rather than what we should *do*” (Darwall 2003, p.1). It is an account of “ethically deep aspects of human life” that stands in contrast to morality as practiced as an irreconcilable dichotomy between competing conceptions of ‘good conduct’ (MacIntyre 2007), focusing instead on the character traits necessary to lead a ‘good life’ (Darwall 2003, p.1). These are not traits which individuals are morally obligated to obtain, but rather those towards which we may aspire and value as ‘good’.

With this said, virtue ethics can provide guidance for moral action by connecting the acceptability of actions to the character of the actor (Oakley 2007, p.87). Right actions are those which the virtuous person would perform. Virtue ethics moves beyond the limitations of moral theories focusing on right actions (Darwall 2003, p.3), focusing instead on how the meaning of a ‘good life’ is derived from traits of the person living it, and how these traits contribute to ‘good’ actions. Justification by reference to virtuous character creates a very

broad guide for actions which must be refined by defining specific virtues (Oakley 2007, p.87), which can be further specified for individual practices (MacIntyre 2007).

4.3.1 Virtues and Moral Practices

Of the modern virtue ethicists, Alisdair MacIntyre's account has much to offer in terms of understanding how virtues help define the ends of specific social activities as medicine. For MacIntyre, virtues are defined against the ends of a practice, which requires practitioners to fulfil a certain role conducive to those ends. A practitioner filling the role well, or exercising 'good' practice, is said to be virtuous. The virtues are therefore traits which dispose the practitioner to fulfilling the ends of the practice. They are not solely this, however; the ends of the practice can only be conceived within a broader conception of good human nature, or *telos*, which defines a good life (MacIntyre 2007, p.273). A good life is one spent attempting to define and pursue *the* good life; the *telos* of humans can therefore only be conceived of within a narrative account of life as a quest for the good life. Such a conception of life only makes sense within a particular moral tradition, understanding of which defines the third piece of an adequate definition of virtues according to MacIntyre (MacIntyre 2007, p.187).

Of the three pieces of the account, practices are the most important in that they are the context in which virtues are realised and defined, albeit incompletely (MacIntyre 2007, p.191), according to a unique history and norms. MacIntyre defines a practice as "any coherent and complex form of socially established cooperative human activity through which goods internal to that form of activity are realised in the course of trying to achieve those standards of excellence which are appropriate to, and partially definitive of, that form of activity, with the result that human powers to achieve excellence, and human conceptions of the ends and goods involved, are systematically extended" (MacIntyre 2007, p.187). This complex definition reveals that for an activity to be called a practice (1) it must have 'internal norms', or standards of evaluation defined by the ends and history of the practice, revisable over time by practitioners (MacIntyre 2007, p.190), through which good activity can be identified, and (2) engaging in the activity must develop in practitioners a sense of how the goods of the practice are defined, and the abilities or character traits necessary to achieve those goods.

The character traits which pre-dispose practitioners to good actions are referred to as virtues. Limited to practices, MacIntyre defines a virtue as "an acquired human quality the possession and exercise of which tends to enable us to achieve those goods which are internal to practices

and the lack of which effectively prevents us from achieving any such goods” (MacIntyre 2007, p.191). Virtuous behaviour shows how the ‘good’ is realised through actions, but the ‘good’ is defined prior to the virtues. The definition of a trait as a virtue therefore depends upon some conception of the ‘good’ internal to a practice. Ethical assessment from the perspective of virtue means that actions are assessed in terms of whether they demonstrate the possession of virtues by the actor; actions are a reflection of character, which provides a basis for criticising the actor and act for in terms of how far they realise the ends of the practice or the good life.

The central virtue in determining whether an actor is virtuous is *phronesis* (MacIntyre 2007, p.158). Without it, other virtues cannot be exercised, as *phronesis* is the ability to make good judgments in particular cases, or in choosing between different courses of action conducive to realising the ends of the practice (Pellegrino & Thomasma 1993, p.84; MacIntyre 2007, p.154). Judgments are good because the person possesses other virtues; *phronesis* allows him to make good judgments by recognising “those ends that which are genuine goods for man” in different courses of action (MacIntyre 2007, p.154). The reasoning process behind actions, informed by virtues possessed by the actor, is therefore crucial in understanding whether a particular action is ‘good’—those possessing *phronesis* are more likely to act virtuously.

4.3.1.1 Internal and External Goods

When speaking of the goods of a practice a distinction is drawn between internal and external goods. The former are those goods which are fully comprehensible only by members of the practice, and can be expressed only in terms of the vocabulary, history or standards of evaluation of the practice (MacIntyre 2007, p.188). By becoming a member of a practice the individual learns and is judged by the standards of excellence unique to it (MacIntyre 2007, p.190). The latter are any goods comprehensible outside this framework and often refer to physical or social goods such as “prestige, status and money” (MacIntyre 2007, p.188), as well as utility (MacIntyre 2007, p.198), power and efficiency. The crucial difference between the two is that the only way to achieve an internal good is by engaging in that particular practice, whereas external goods can be achieved by some other means (MacIntyre 2007, p.188). This means that external goods are finite—one person gaining an external good means there is less of it to go around. In contrast, internal goods are “good for the whole community” of the practice (MacIntyre 2007, pp.190–1), where a practitioner achieving an internal good is beneficial for the practice itself.

The internal goods of a practice are a reflection of the virtues of the practice; they are the effects of virtuous behaviour which help realise the ends of the practice. Internal goods are defined and understood in terms of the unique history of the practice apart from which the ends and virtues of the practice cannot be defined. In joining a practice one is judged by the standards of the practice established and updated throughout its history by practitioners, based on self-reflective evaluation of their experiences with the practice. Internal goods have a history outside of which they do not make sense, or cannot be fully understood. MacIntyre uses the example of playing chess—through repeated training and playing against a difficult opponent, “analytical skill, strategic imagination and competitive intensity” are developed, contributing to a fuller appreciation of the nuances and goods of playing the game (MacIntyre 2007, p.188). This type of appreciation—the appreciation of a practice performed well, which can only be understood in this example by the master chess player—is the type of ‘good’ referred to with internal goods.

Practices are linked to institutions through the pursuit of external goods necessary to sustain the practice and its realisation of internal goods. Practices and institutions form a “single causal order” in which the goods internal and external to the practice are tied together, with practitioners ideally concerned solely about the former and the institution, the latter. A tension exists because the realisation of internal goods may prevent the achievement of external goods (MacIntyre 2007, p.196); for example, when providing a patient sufficient care conflicts with the efficiency goals of a hospital. In this relationship the “cooperative care for common goods of the practice is always vulnerable to the competitiveness of the institution,” meaning that the primary role of virtues is to protect a practice, through exercise of virtues such as justice, courage and truthfulness, from the “corrupting power of institutions” (MacIntyre 2007, p.194). The relationship is not merely one of corrupting power, however; practices must remain virtuous to justify the continued existence of the institution. If practices fail to act as ‘ethical’ brakes on the institution, both will eventually fail. The tension and co-dependence seen in the practice/institution relationship mirrors that of the lifeworld/system (see: Section 3.4.1).

In this relationship the ethical importance of virtues comes into view: without virtues both the internal and external goods of the practice cannot be realised, failing the individuals provided for by the practice (e.g. patients in medicine) while also failing to sustain the practice, its internal goods and history apart from which it cannot be understood. It is therefore necessary

when assessing PHM from the perspective of virtue ethics to consider the ‘corrupting’ influence of PHM as an extension of institution values, or concerns with external goods, which may ‘colonise’ medical decision-making or the lifeworld of the patient via PHM (see: Section 3.4.1.1).

4.3.1.2 A Narrative Life and *Telos*

Virtue ethics can be criticised for a broad definition of virtue, by which virtues are cultural- or practice-relative and open to maleficent traits, leading to moral relativism. Another way to understand this criticism is that modern virtue ethics lacks a rational conception of the good because classical metaphysical conceptions of human good or *telos*, such as those of Aristotle or Aquinas (cf. Darwall 2003; MacIntyre 2007), are not empirically defensible (Pellegrino & Thomasma 1993, p.13). Without an alternative rational conception of the good, virtue ethics cannot defend any definition of the virtues or virtuous behaviour as conducive to the good life or the ends of a particular practice.

To answer this criticism, MacIntyre emphasises the need for a complementary “moral law” for any account of morality based on virtues (MacIntyre 2007, p.200). For Aristotle, the complementary moral law appears to be a *telos* based on metaphysical biology (MacIntyre 2007, p.184). In contrast, MacIntyre claims that virtues must be defined with both the ends of the practice and a conception of *the* good life in mind. These components explain what practitioners are working towards when engaged in the practice, and how the goods of the practice contribute to *the* good life.³⁴ MacIntyre argues that a conception of *the* good life, or the *telos* of humanity, is necessary to fully understand any virtues, including those relative to a particular practice:

“If a human life is understood as a progress through harms and dangers, moral and physical, which someone may encounter and overcome in better and worse ways and

³⁴ It may also be possible to address this criticism from a Habermasian discourse ethics perspective (e.g. (Habermas 1984; Habermas 1985), from which the ends of moral practices are socially constructed through discourses in which participants bring different conceptions of how to define the good life and the ends of the practice (which serve the good life) to the discourse, in which a compromise is reached to define the ends of the practice for cooperative social life by questioning the validity claims made in the discourse. Although a fundamentally different approach to ethics, a discourse approach may be helpful in explaining how the ends of a practice are refined over time. If the ends of the practice are defined by discourse which is itself a model for ethical decision-making, the discourse provides a rational conception of the good for the practice in question. This idea is not explored further in the thesis, although it may provide an alternative way to justify a practice-based approach to virtue ethics as containing a rational conception of the good life apart from *telos*-based accounts. The discourse itself may be seen in discourses between professional bodies, for example over accreditation requirements.

with a greater or lesser measure of success, the virtues will find their place as those qualities the possession and exercise of which generally tend to success in this enterprise and the vices likewise as qualities which likewise tend to failure” (MacIntyre 2007, p.144).

For MacIntyre, the *telos* of human life can only be understood when conceiving of human life as a unified narrative quest along which the individual pursues and learns about the virtues necessary for *the good life*, the relative weighting of goods (MacIntyre 2007, p.219), and the “meaning of one’s life” by “living and reflecting upon it” (Edgar 2005, p.168). So defined, the *telos* of humans is to engage in a lifelong quest to understand *the good life* and the virtues necessary to understand and achieve it (MacIntyre 2007, p.219), with the virtues only comprehensible within the broader social tradition of that life (MacIntyre 2007, pp.273, 275). The internal goods of practices cannot be understood apart from the narrative of life, and the social tradition in which that life occurs.

On this basis MacIntyre expands the definition of virtue beyond the confines of practice:

“The virtues therefore are to be understood as those dispositions which will not only sustain practices and enable us to achieve the goods internal to practices, but which will also sustain us in the relevant kind of quest for the good, by enabling us to overcome the harms, dangers, temptations and distractions which we encounter, and which will furnish us with increasing self-knowledge and increasing knowledge of the good” (MacIntyre 2007, p.219).

This definition emphasises that virtues pre-dispose practitioners to achieve practice internal goods, while sustaining “communal identities” through which individuals pursue *the good life* as part of a broader social tradition. As such, virtues provide “necessary historical context” for the comprehension of the goods of practices and human life (Pellegrino & Thomasma 1993, p.11).

While the three-part definition of virtues as occurring within practices, the narrative life and a social tradition is seen by MacIntyre as fulfilling the need for a rational conception of ‘good’ against which virtues can be defined, it remains an incomplete answer to the criticism until an account is provided of the social tradition in which *the good life* is sought. MacIntyre has acknowledged this much in his existing work (MacIntyre 2007). The difficulty with the narrative life approach to human *telos* is that it appears to allow for a plurality of virtues across different social traditions—different people attempting to define and achieve *the good life*, while all coming to understand and practice virtues, are not guaranteed to arrive at the same

set of virtues. This in itself is not a problem—the quest is understood as the important component of *the* good life for humans—but it does little to allay concerns of vices being mistaken for virtues until it is understood how a social tradition confines the traits which can legitimately be called virtues.

The outcome of this argument may not be important for the task at hand, as it can be argued that when applying virtue ethics to specific ethical problems, defining virtues against the ends of the relevant practice(s) alone is sufficient. Traits which contribute to good practice can be seen as sufficiently desirable in terms of the ends of the practice towards which they contribute. This position assumes the ends of the practice in question are good, or part of the good life, however it is defined. The purpose of fitting practices into a broader conception of human *telos* is to protect against recognising maleficent character traits as virtues (Pellegrino & Thomasma 1993, p.190), thus justifying the virtues as a rational basis for ‘good’ action. For the purposes of this project it does not seem necessary to debate the truth of MacIntyre’s account of the *telos* in detail. Rather, the ends of medicine can be seen to fit into many possible conceptions of *the* good life (see: Section 4.3.2), including MacIntyre’s (Pellegrino & Thomasma 1993). The assumption made here is not radical; a defence of MacIntyre’s *telos* would only be necessary if doubt exists that medicine, as a social practice, does not serve a desirable social good, meaning that virtues defined in reference to the ends of medicine may be morally deficient. Whether or not MacIntyre’s account of human *telos* is successful, conceiving virtues as traits conducive to good practice helps in applying the concept to specific problems, such as those faced with PHM.

4.3.2 Ends of Medicine

The implications of PHM can only be assessed in terms of virtue once the ends of medicine are understood. Medicine is a practice by MacIntyre’s definition (Pellegrino & Thomasma 1993), as shown by internal standards of good medical care (cf. General Medical Council 2008; General Medical Council 2013) and accreditation processes which uphold these standards. The *telos* of a practice can be understood through critical examination of its internal goods or norms of evaluation; for medicine, these norms can be found in the doctor-patient relationship (Pellegrino & Thomasma 1993, p.52). As seen in this relationship, “the ends of medicine are...the restoration or improvement of health and, more proximately, to heal, that is, to cure illness and disease or, when this is not possible, to care for and help the patient to live with residual pain, discomfort or disability” (Pellegrino & Thomasma 1993, pp.52–3). Broadly

speaking, the end of medicine is to guarantee the health of a society and individuals within it (cf. World Health Organization 1948; Fulford 1989), achieved through ‘good’ medical encounters with individual patients (cf. General Medical Council 2013). In pursuing these ends in the doctor-patient relationship moral and technical capacities must work together in the interests of the patient because medical activity affects individuals with moral worth and interests.³⁵

Health is a fundamental good valued across many contexts, including personal, social and economic life, related to the maintenance and well-being of the whole person. Without health personal plans cannot be made, projects pursued, or identities created without restrictions imposed by a physical, mental or social ailment (cf. Edgar 2005). Health is therefore a prerequisite for the realisation of other human goods. Despite the difficulties of defining health and illness, medicine is broadly recognised as a practice to promote health (Fulford 1989; Pellegrino & Thomasma 1993; Schotsmans et al. 1998), thereby working towards a fundamental good. A lack of agreement on a ‘correct’ definition of health, reflected in debates on the topic (cf. Fulford 1989; Petersen 1997; Clarke et al. 2003), does not undermine the fundamental value of health to human life.

4.3.2.1 Medicine as a Moral Community and the Healing Relationship

Medical relationships can be understood as a manifestation of medicine as a practice, in which expectations are attached to social and professional roles, judged in terms of practice-relative virtues. Medicine can be considered a moral practice because its members form a community which shares a common goals and moral obligations (Pellegrino & Thomasma 1993, p.3; Morris 1996; Schotsmans et al. 1998), meaning they are “guided by some shared source of morality—some fundamental rules, principles, or character traits that will define a moral life consistent with the ends, goals, and purposes of medicine” (Pellegrino & Thomasma 1993, p.3). The virtues of a practice help ensure its ends are met over time (Pellegrino & Thomasma 1993, p.32) by combating the corrupting influence of institutions and external goods (see: Section 4.3.1.1).

³⁵ These ends can be realised through different types of doctor-patient relationships; an influential account posits four models of the relationship in terms of the balance between physician and patient power in decision-making and the influence of values: paternalistic, informative, interpretive and deliberative, with the latter being preferred (Emanuel & Emanuel 1992) and very similar to shared decision-making models preferred elsewhere (e.g. (Pellegrino 2002; Karnieli-Miller & Eisikovits 2009).

Medicine is a moral practice out of necessity because of the moral obligations inherent to the healing relationship (Schneiderman et al. 1990; Pellegrino & Thomasma 1993, p.3; Morris 1996; Schotsmans et al. 1998). Membership in the medical *profession* means committing oneself to the moral obligations of providing care, resulting from the patient *trusting* the clinician to use medical expertise in his best interest. In clinical encounters the physician, as a practitioner of medicine, “voluntarily promises that he can be trusted and incurs the moral obligations of that promise” (Pellegrino 2002, p.379). Importantly, the term ‘physician’ as used here can indicate a lone practitioner (as is implied in Pellegrino and Thomasma, 1993), a care team consisting of multiple GPs, nurses, nurse practitioners, consulting specialists, and other members of the medical profession. Where care is increasingly provided through care teams, the boundaries of the healing relationship should be expanded to include other members of the profession bound by the same moral obligations as the physician created by participation in the healing relationship.

The virtues of medicine can be built upon five characteristics of the healing (Pellegrino & Thomasma 1993) or caring relationship (Schotsmans et al. 1998) between physicians and patients that create moral obligations (Pellegrino & Thomasma 1993, pp.35–6, 42–4):

1. **Vulnerability and Inequality** – Patients experience a loss of control to define and pursue personal goals, and may experience emotional stress, fear, worry, and anxiousness (Morris 1996). The immediate goal of life becomes the restoration of health and well-being by relieving or curing symptoms. When symptoms are sufficiently severe, an unequal relationship is created in which the patient is forced to seek the help of an individual with privileged medical expertise in the pursuit of a return to health. The physician has an obligation to not use his expertise to exploit the vulnerable patient, for example by recommending a treatment without justifying the decision and explaining its consequences to the patient (Pellegrino & Thomasma 1993, pp.35–6).
2. **Fiduciary Nature** – The patient must place trust in a chosen physician and reveal aspects of himself and his life to allow diagnosis and healing. The physician encourages the patient’s trust by taking an oath upon entering the profession to act in the best interests and welfare of the patient. Physicians have a moral obligation to make use of the information and access provided by the patient in a trusting relationship in the patient’s best interests, and not for self-interest

(Pellegrino & Thomasma 1993, pp.35–6, 42–4; Heritage et al. 2006, p.355; Karnieli-Miller & Eisikovits 2009, p.2).

3. **Nature of Medical Decisions** – Medical decisions are a combination of technical and moral features. The physician’s diagnosis and treatment of the patient must be technically accurate to promote physical health (Pellegrino & Thomasma 1993, pp.35–6, 42–4). However, decisions should also support the patient’s moral well-being or autonomy as a being with moral value, in the sense that the decision should match with the patient’s moral values (e.g. Beauchamp & Childress 2009), assessed through dialogue with the patient. This feature of the relationship creates a moral obligation to learn about the patient’s values, and structure treatment accordingly (Karnieli-Miller & Eisikovits 2009, p.2) to produce the best outcomes for both physical and psychological well-being (Heritage et al. 2006, p.354), and to not exploit the vulnerable patient with technically sound but morally incongruent treatments (Pellegrino & Thomasma 1993, pp.35–6, 42–4). To do the latter would be to act strategically toward the patient, for example by using confusing or technical language to convince the patient of a treatment poorly matched to his values (Edgar 1997, p.32; Scambler & Britten 2001, p.54), ignoring the psycho-social aspects of well-being by decontextualising the clinical encounter (see: Section 4.3.4). The doctor therefore has an obligation not to engage in this sort of strategic action, knowingly or concealed (Scambler & Britten 2001, p.54), meaning communicative action must ground the healing relationship (see: Section 6.1.3.3.1).
4. **Characteristics of Medical Knowledge** – Medical knowledge is non-proprietary. To ensure a sufficient quantity of health professionals, societies provide physicians with privileged knowledge and access to human bodies necessary to gain medical expertise, and may limit recognition of practitioners of medicine to individuals thus trained. Physicians have a moral obligation to act as stewards to this knowledge, ensuring it is readily available to others, used ethically in the treatment of patients, and not used purely for self-interest, because of the implicit social agreement through which they originally obtained the knowledge (Pellegrino & Thomasma 1993, pp.35–6, 42–4).
5. **Moral Complicity** – The physician is the channel through which medical interventions flow to the patient, in the sense that the physician must agree to

each intervention carried out. In this position the physician has a moral obligation to act as a gatekeeper, safeguarding the patient's well-being and acknowledging his complicity in any interventions carried out (Pellegrino & Thomasma 1993, pp.35–6, 42–4).

The characteristics of the healing relationship described here are not beyond question. The experience of illness as vulnerability and inequality can be criticised in that it only seems to apply to acute problems with potential cures. While chronic illness may start out similarly, patients must form different identities based around amelioration of symptoms rather than cures to make sense of the effects of the illness on their life (Edgar 2005). Chronic illness need not be experienced in such an emotionally negative or disempowering way, as suggested by disability theory (cf. Page-Hanify 1980; Nussbaum 2007). Despite this shortcoming in the understanding of illness, the fundamental nature of the medical relationship as one in which a patient in need seeks the expertise of the physician is beyond question. In seeking out medical help, the patient is agreeing to reveal himself and private aspects of his life to the physician with medical expertise in the pursuit of health. The relationship is an exchange of sensitive goods for improvements in quality of life, one which the patient is 'forced' to engage in if medical expertise is desired in pursuit of a return to health.

Regarding the fiduciary relationship, if modern medicine is characterised by 'empowered' patients eroding the privileged position of physicians as 'experts', trust cannot be assumed to exist whenever healing occurs. Despite this, a certain level of trust is implicit in the patient's decision to allow himself to be examined by the physician, and to follow his recommendations. Furthermore, although medical information is increasingly available through other mediums, the role of expertise as an indication of fidelity to trust does not change. Physicians are consulted not merely as 'encyclopaedias of knowledge', but rather as trained experts capable of subjective evaluation and understanding the patient as a socially embodied person with a history and values (Emanuel & Emanuel 1992, p.2225), suggesting that designing a healing relationship primarily around patient autonomy risks reducing the physician to a mere service-provider, incapable of exercising the full range of medical virtue (see below).

For the purposes of assessing PHM in terms of virtue, a more robust defence of the healing relationship and the ends of medicine is not necessary. So long as medicine is seen as occurring primarily through the relationship between physicians and patients, and it is

recognised that medicine as a practice has internal goods (and therefore, virtues) that are pursued in this relationship, PHM can be assessed without the need to defend specific moral obligations or virtues as true across all medical relationships. If PHM reduces opportunities to realise the virtues of medicine in encounters with patients, it can be criticised for undermining virtuous practice in medicine.

4.3.3 Medical Virtues

Virtues are defined against the ends of the practice which they are meant to serve. For medicine, these ends are providing adequate care for a society, consisting of individual patients, in terms of physical and mental health and well-being. These ends are realised through the healing relationship, the nature of which suggests certain moral obligations in meeting the ends of the practice.

As with all practices, *phronesis* (MacIntyre 2007, p.154; Widdershoven & van der Scheer 2008) or prudence (Pellegrino & Thomasma 1993) is a central virtue in medicine, without which other virtues cannot be incorporated into behaviour through virtuous acts. Justice, truthfulness and courage are also necessary to protect medicine from the corrupting power of medical institutions (e.g. MacIntyre 2007, p.192), including hospitals, paying organisations and government departments. These three core virtues are necessary for continuous revision of standards of excellence and internal goods by practitioners, which requires critical self-reflection on the relationship between one's actions and the norms of the practice (MacIntyre 2007, p.191), or the institutional influence on the definition and realisation of norms.

Justice is defined broadly as “the strict habit of rendering what is due to others” (Pellegrino & Thomasma 1993, p.92), or “the virtue of rewarding desert and of repairing failures in rewarding desert within an already constituted community” (MacIntyre 2007, p.156). To be just, standards for treating people in a community must be “uniform and impersonal,” meaning it is unjust to favour personal acquaintances. In social or national healthcare systems, justice can be applied to the distribution of medical resources (e.g. pharmaceuticals, treatments, clinical encounters) in a manner fair to all stakeholders. Justice is not merely a quantitative notion, by which all stakeholders receive an equal share, but instead requires matching resources to the needs of the patient, and making judgments between the relative importance of different needs.

Fidelity to trust and beneficence can also be understood as core virtues unique to medicine (Pellegrino & Thomasma 1993, pp.71, 156) because of the need for trust in healing relationships (see: Section 4.3.2.1). A trusting relationship needs to develop over time between the virtuous physician and patient, in which the values, expectations and thoughts on illness and appropriate medical care are shared. The patient must at a minimum believe the physician is acting beneficently, or in his interests and well-being (Pellegrino & Thomasma 1993, p.156), to some degree for trust to exist.

Other less central virtues include compassion, fortitude, integrity and temperance.

Compassion is the trait of a physician which allows him to 'enter the perspective' of the patient, to understand how the patient's values, expectations of care, social, emotional and physical well-being affect his experience of illness, and to customise his care and recommendations to the needs of each patient as a unique individual (Pellegrino & Thomasma 1993, pp.79, 81). Compassion may also necessitate the promotion of health-related values and deliberation with the patient to convince him of the best intervention in terms of fit between health outcomes as perceived by the physician and the patient's values (Emanuel & Emanuel 1992, p.2226) Fortitude is a form of moral courage, by which an individual is willing to "suffer personal harm for the sake of a moral good" (Pellegrino & Thomasma 1993, p.109) such as a physician refusing to act in accordance with institutional rules which would be detrimental to his patient's well-being, risking harm to his career and professional membership. Fortitude can create an obligation for physicians to speak out against the potential harms of new institutional policies, technologies or treatments for their patients. Temperance is the restriction of behaviour in a practice to meet the moral obligations of that practice. It can be used synonymously with virtue itself, but is distinct as a character trait of the virtuous physician (Pellegrino & Thomasma 1993, p.117) who suppresses self-interest in treating patients. Without such restraint other virtues cannot be practiced.

Integrity is the possession of all virtues combined with the ability to discern between moral principles in choosing appropriate actions conducive to the good of medicine in different situations (Pellegrino & Thomasma 1993, p.127; Edgar & Pattison 2011, p.102). It is the core virtue of the narrative quest for the good life, and can be seen in a life of virtuous behaviour (MacIntyre 2007). Integrity can be exercised when a physician promotes the patient's interests and welfare in the face of institutional pressure (Edgar & Pattison 2011, p.94), for example by not sending a patient home early from hospital. Edgar and Pattison define

integrity as “the capacity to deliberate and reflect usefully in the light of context, knowledge, experience and information (that of self and other) on complex and conflicting factors bearing on action or potential action” (2011, p.102). Integrity is therefore perhaps indistinguishable from *phronesis*, temperance and fortitude.

PHM may change the nature of the healing relationship by affecting how and when care is provided, and thus how and when virtues may be realised in care. It is thus the implications for the healing relationship, recognised as the arbiter through which virtues are realised, that are important for developing a conceptual understanding of PHM as a technology which may inhibit the realisation of medical virtues. The content of the virtues themselves is less important for a conceptual framework, although their meaning must be fleshed out for future instances of application and context-specific analysis, in which PHM is seen to inhibit particular virtues in a particular relationship.

4.3.4 Implications for PHM

The healing relationship changes for patients cared for by PHM. Groups responsible for PHM outside of the physician or care team, including service providers, data custodians and institutions, enter the relationship as new stakeholders for whom the moral obligations derived from the healing relationship may not be recognised, meaning PHM is not necessarily seen as an extension of the healing relationship. The patient’s ‘vulnerable’ position in the relationship may also not be evident to these new stakeholders. Face-to-face encounters may be reduced if care can be provided more efficiently (in the eyes of care commissioners or paying organisations) via monitoring and remote services. Even if the frequency of clinical or care encounters remains the same, new interactions are created between patients and non-physician stakeholders which are not necessarily bound by the moral obligations of the healing relationship.

PHM data also affects encounters with physicians as a new tool to assess and diagnose the patient. The healing relationship moves out of the physician’s office and hospital as PHM is installed in homes or worn by users, co-existing whenever monitoring is switched on. Rather than a discrete series of events, the healing relationship may be a constant process, with face-to-face or remote encounters with professionals linked together by monitoring.

It is unclear whether this model of the healing relationship is conducive to the realisation of virtues in the same way as face-to-face encounters, even when face-to-face encounters are

not reduced through the use of PHM. As a mediator placed between the physician and patient, PHM changes the dependencies between physician and patient by turning some degree of the patient's care over to monitoring, meaning the patient's health and well-being are to some degree reliant upon the quality of monitoring provided by a technological application rather than the physician. Patients will have to trust PHM or service providers to some degree to acquiesce to use; whether this trust is similar in nature to trust in the healing relationship is unclear. As discussed in reference to security (see: Section 3.2.1.1.2) trust can exist between a user and a system or the system's operator. The healing relationship model is applicable when trusting the individual or organisation providing PHM. However, such trust may be misplaced if service providers do not experience the same moral obligations as physicians as members of medicine as a profession.

This aspect of PHM inhibiting virtuous practice hinges on the model of service provided by PHM; if delivery is handled entirely by existing care teams bound by the moral obligations of the healing relationship, the problems created by 'non-virtuous' stakeholders entering the relationship are reduced. However, if care is increasingly delivered by non-physicians, for example if PHM is provided through private channels or on a commercial basis outside of medicine, the moral obligations of the physician are temporarily displaced without clearly changing the patient's experience of illness (e.g. fear, helplessness, dependency) or expectations of the healing relationship. The features of the healing relationship which initially create moral obligations for medical professionals are not eliminated by the move to monitoring, meaning the same moral obligations exist pre- and post-monitoring. As a result, the patient will still expect moral obligations to be fulfilled by the stakeholder(s) replacing or joining the physician in the healing relationship, without any guarantee that the new stakeholders (e.g. monitoring systems, service providers, data custodians) will be capable or willing to act virtuously towards the patient. Therefore, the opportunities for virtuous medical practice are reduced by the move to care via monitoring.

In such a relationship in which medical virtues are increasingly absent there exists a risk that patients will engage in healing relationships with physician-proxies, placing trust in monitoring systems or service providers assumed to be bound by the same moral obligations as physicians. This risk can be seen as a continuation of the 'deprofessionalisation' seen in medicine in the past, during which time "character traits requisite for the protection of the welfare and interests of patients" have been increasingly lost among physicians (Pellegrino

2002, p.384). The concept of a healing relationship between physician and patient may not accurately describe PHM-mediated care, necessitating a revised account of the moral obligations, and thus virtues, of medicine in which care via monitoring is the norm (e.g. chronic illness management). It may be that a healing relationship between physicians and socially embodied patients, in which the values and expectations of the patient influence the course of care, occurs less frequently or not at all in PHM-mediated care. PHM can be said to undermine the virtues of compassion and fidelity to trust in this instance, whenever physicians are denied opportunities to speak with the patient, empathise with and understand their point of view and values.

Virtue ethics can help make sense of colonisation from the view of the patient's lifeworld in terms of identity and pursuit of *the* good life. If we accept MacIntyre's narrative account of the good life (see: Section 4.3.1.2) PHM colonises the patient's identity through medicalisation of his narrative. Users must make sense of their lives as a 'chronic patient' or 'at-risk patient' due to monitoring (cf. Edgar 2005, p.169). Through this process the patient becomes involved in the practice of chronic illness, by which his narrative and identity must be constructed within the "unavoidable framework" of chronic illness (Edgar 2005, p.169). Acts which contribute to the adoption and sustenance of chronic identities, such as the "exclusive reliance upon measurable outcomes in assessing the management of chronic illness" (Edgar 2005, p.171) made possible by PHM data, can therefore be criticised for interfering with the pursuit of a virtuous life by colonising the patient's understanding of the good life. PHM contributes to 'identity colonisation' through the translation of physiological parameters and behaviours into data amenable to remote analysis and categorisation, contributing to remote and self-management of the illness.

The latter point hints at a second opportunity for the inhibition of virtuous practice created by PHM. Monitoring physiological parameters reproduces a certain kind of health, by which the patient's medical status is increasingly evaluated in terms of parameters amenable to monitoring. The availability of PHM data creates a risk that monitoring data will increasingly colonise the healing relationship, reducing the importance of contextual factors to health or the view of the patient as a socially embodied person. If PHM can deliver physiological readings necessary to diagnose the patient's physical ailment, the temptation exists to engage less and less in face-to-face encounters during which trust is traditionally developed, or to trust the patient's account in those encounters. PHM can create a 'veneer of certainty', in

which 'objective' monitoring data is taken to represent a true representation of the patient's situation, losing sight of the data collection context. The outcome of this may be ignorance of the patient's social, mental and emotional state, or 'decontextualisation' of the patient through which the psychological aspects of well-being describable only by the patient are lost from the clinical encounter (cf. Edgar 1997, p.35), which fails to recognise the necessity of such knowledge in shared-decision making models of clinical care (Karnieli-Miller & Eisikovits 2009, p.2). In pursuit of external goods, institutions and physicians may be tempted to 'close down' discourses with patients through appeal to 'objective' physiological data, thus ignoring the (meaning of the) lifeworld of the patient.

Decontextualisation can be conceived of as the inhibition of virtuous practice in medicine caused by monitoring as a model of care, rather than through a reduction in face-to-face encounters or the introduction of new stakeholders into the healing relationship. The relative importance of this risk can only be determined in the context of specific relationships: for example, PHM data may instead provide a starting point for discourses in which the patient has greater knowledge of his condition and monitoring data. The potential benefits of PHM in this regard, by which monitoring can empower patients in the healing relationship or promote patient autonomy by moving care out of hospitals and into homes in which patients are less restricted in terms of activity and identity (see: Section 3.4.1.3), for example, need also be considered in future discourses informed by the conceptual framework.

4.3.5 Conclusions

From the perspective of virtue ethics the ethical acceptability of PHM can be summarised as an if-then argument: if PHM reduces the chances of being a virtuous physician, or for patients to be treated by virtuous practitioners, then it is ethically problematic because it reduces opportunities to ensure the patient's entire physical and mental health and well-being achieved through treating the patient as a socially embodied person in the healing relationship. The relative importance of maintaining 'good' medical practice in any particular situation in which PHM may be deployed remains to be determined on a case-by-case basis; what the account here explains is how PHM affects these goods, not the relative importance of their continued realisation by physicians.

Virtue ethics suggests that PHM can be seen as ethically harmful if it undermines the realisation of virtues necessary to achieve the ends of medicine as a moral practice. But how

exactly would PHM achieve this? To answer this question, it is necessary to explore the implications of theories of surveillance for our understanding of PHM and how it may undermine the realisation of medical virtues in the healing relationship.

4.4 PHM as Medical Surveillance

PHM broadens the scope of health and medicine by allowing for various parameters of private life to be monitored in the pursuit of better health. Previously closed off areas of life may be opened to medical scrutiny for the sake of identifying, treating and managing health conditions. The quantity and quality of information available to clinicians and medical institutions in delivering care increases, and alternative means for care delivery and data collection are established. PHM has the potential to fundamentally change the delivery of medical care through the creation, analysis and transmission of data about the private lives, environments and behaviours of patients.

In these terms, PHM can be understood as a surveillance technology. Following Lyon (2001a, p.2), surveillance is defined here as “any collection and processing of personal data, whether identifiable or not, for the purposes of influencing or managing those whose data have been garnered.”

4.4.1 Big Brother

In the reviewed literature, PHM was only rarely seen as a technology of surveillance (see: Section 3.2.1.2.1). Much of the discourse employed the ‘Big Brother’ metaphor, based on George Orwell’s *1984*, according to which users think PHM is deployed by a large ‘sinister’ organisation or government to monitor and control the private lives citizens (e.g. Welsh et al. 2003; Brey 2005; Percival & Hanson 2006; Essén 2008; Bowes et al. 2011; Sorell & Draper 2012). This metaphor arguably bears little relevance to modern surveillance, which resembles an ‘assemblage’ of systems implemented by many small organisations and stakeholders for a variety of purposes (Haggerty & Ericson 2000). For the metaphor to be true to the source material a state would need to have a policy of “policing...of people’s political opinions or personal views” through the use of PHM, which is not apparent in the UK (Sorell & Draper 2012, p.40) or other European nations (see: Section 1.2.1). Although the metaphor may help users express concerns over privacy and the implications of surveillance (Percival & Hanson 2006; Sorell & Draper 2012), it detracts from current discourse by assigning an unsubstantiated desire for social control to service providers, which would require supporting

evidence from specific contexts of use, addressing the provider's motives. Sinister motives may also be attributed by users to technologies and organisations engaging in any level of ICT assisted monitoring (cf. Rule et al. 1991; Lyon 2007, pp.57–9), which distracts from the benefits of seemingly benign uses of personal data at an organisational level which assist in 'understanding' data subjects through categorisation and prediction (Lyon 2007, p.162) (see: Section 4.4.3).

4.4.2 The Panopticon

Beyond 'Big Brother', several accounts of PHM as surveillance in current discourse can be traced to Foucault, by which PHM is a tool of disciplinary power and rational control (cf. Foucault 2012). Kenner (2008) examined the politics of PHM as a surveillance technology supporting aging in place, with implications for the autonomy of the elderly in having their choice of behaviours at home limited, and the increased social control offered to medical professionals and carers by linking behavioural changes with health conditions via monitoring (Kenner 2008, p.263). Elsewhere, in-vivo PHM was seen to limit how patients behave and self-identify due to self-discipline stemming from the perception of always being watched (Light 2010, p.594). A similar type of control is seen when PHM is treated as 'somatic surveillance', defined as the practice of recording bodily information as data which can be transferred, effectively turning "bodies into 'nodes' on larger information networks." Once gathered, the information can be used to suggest interventions "into body functions through various sociotechnical feedback mechanisms," exhibiting control over the behaviours and choices of patients (Monahan & Wall 2007, pp.154–5). These accounts of PHM as bodily surveillance with disciplinary power are instructive, and necessitate closer analysis of the underlying metaphor of PHM as a type of modern panopticon (cf. Foucault 2012).

The panopticon is a hypothetical prison imagined by Jeremy Bentham (1791). In the panopticon cells are assembled around a central guard tower such that a single guard can see into all cells. The tower has blinds or blacked out windows which prevent the prisoners from knowing when they are being watched, meaning they must assume they are always being watched and behave accordingly. In the panopticon disciplinary power is exercised from within, as prisoners come to act as their own guards, constantly reminded of the possibility of being watched and the expectations of the watcher (Foucault 2012). Prisoners "reflect upon the minutia of their own behaviour" in an attempt to actively transform themselves (Haggerty & Ericson 2000, p.607), internalising the disciplinary power represented by the tower (Foucault

2012). When surveillance technologies are compared to a panopticon, attention is drawn to the potential for rational control, intended to shape the behaviours of the watched according to the values of the operator (Lyon 2001b, p.175).

The panopticon metaphor is problematic when applied to PHM for several reasons. First, it introduces an element of omniscience to surveillance, by which every action and private moment is perceived as being monitored, a state of affairs surely violating the privacy and comfort of individuals in modern society (Rule et al. 1991, p.321). While such a state could theoretically exist with sufficiently pervasive PHM, perceived omniscience is not apparently a goal of modern systems targeting specific health parameters or, at most, behaviours (see: Chapter 2). Second, it stresses the potential for rational control, distracting from the potential for PHM to subtly influence the behaviours and attitudes of users without overt discipline (cf. Lyon 2007, p.57). Finally, the panopticon gives a one-way account of surveillance, in which the power to monitor and act lies solely with the prison guards, or operators of surveillance. This account fails to recognise the power of the watched in limiting and consenting to surveillance (Lyon 2007, p.73), exercised at a minimum when consenting to health monitoring. Beyond this, PHM data may help patients to express health concerns and ask questions in clinical encounters, with the data seen as an objective record providing evidence to support the patient's claims.

The panopticon is insufficient as a metaphor for modern surveillance (Haggerty & Ericson 2000, p.607), such as PHM, in part because it ignores the possibilities of resistance unavailable to prisoners in a closed disciplinary space. With the exception of in-vivo PHM (Light 2010), users can disable PHM or leave the monitored area (cf. Lyon 2007, p.59) or decline to adopt monitoring technologies. This is true so long as surveillance is not ubiquitous (see: Section 2.3.2.4), or rejection of monitoring carries with it such extensive burdens, for example denial of treatment, to make consent meaningless. So long as the need for consent is upheld, PHM does not possess obvious disciplinary power through which the user's attitudes and behaviours are changed by being 'trapped' in a surveillance space.

The panopticon metaphor helps draw attention to the power implicit in perceptions of being watched, often linked by users to 'Big Brother' and a lack of control over PHM (e.g. Welsh et al. 2003; Percival & Hanson 2006). Behaviour inhibition linked to obtrusiveness (see: Section 3.2.4) may be based on the perception of being watched, causing the user to change his

behaviour to better meet the expectations of the system or the operator. However, other types of power flow through PHM which may cause users to change their behaviours and identities.

4.4.3 Social Sorting: The Power to Categorise

As a surveillance technology, PHM offers the power to sort and treat people differently based on oversight (cf. Gandy 1993; Lyon 2003), or the collection of personal information by which users can be categorised. Surveillance is “a vital means of sorting populations for discriminatory treatment” (Lyon 2003, p.19). This aspect of surveillance suggests ethical concerns do not centre around privacy (Lyon 2001b; Raab 2012, p.384), or the inability to retain control over personal data, but rather the consequences of being categorised (Gandy 1993) by which individuals are placed into groups affecting their future choices in the utilitarian pursuit of efficiency or reduced costs (Lyon 2001b, p.177). Increasing privacy to combat surveillance is not always beneficial to subjects of surveillance (Lyon 2003, p.19) (see: Section 3.3.4), because categorisation can be used to the benefit of those categorised, for example by directing relevant information or recommended interventions to patients.

This type of categorisation is referred to as ‘social sorting’, defined as the classification of people with similar characteristics into groups for different treatment and management (Lyon 2007, p.26). Social sorting draws attention the contribution of surveillance technologies to “the social and economic categories and the computer codes by which personal data is organised with a view to influencing and managing people and populations” (Lyon 2003, p.2). According to Lyon, the grouping of individuals by data collected about them is the primary, frequently automated function of modern surveillance (Lyon 2003, p.13). In current discourse Lyon is used to support claims of living in risk-obsessed societies (cf. Welsh et al. 2003; Kenner 2008), to suggest that specific applications can contribute to surveillance of users and carers (cf. Kenner 2008; Vuokko 2008; Monahan & Fisher 2010), or to argue that surveillance providers carers and family members power over homebound elderly patients (cf. Kenner 2008). The connection between PHM, social sorting, institutional and clinical power over patients has not yet been explored in academic discourse (see: Chapter 3).

Surveillance as practiced today is undertaken by numerous unconnected agencies gathering, analysing and sharing data about individuals for purposes related to marketing, governance and control. Profiles and risk groups are created from surveillance data of individuals and

groups in planning services, predicting behaviours and events, and preventing risks or undesirable consequences (Lyon 2003, p.13). Populations are classified “according to varying criteria, to determine who should be targeted for special treatment, suspicion, eligibility, inclusion, access, and so on” (Lyon 2003, p.20). Categorisation affects the information given to individuals, and the choices available to them in moving through social systems mediated by surveillance (Lyon 2003, p.13). PHM offers medical institutions and clinicians the opportunity to categorise users according to their physiological readings and behaviours. The power in this opportunity cannot be described merely as disciplinary power, through which the patient’s behaviours and identity are changed to better match the values of service providers.

4.4.3.1 Bio-Power

The identification of something as a disease, by which physiological patterns and social practices can be transformed into illnesses, is a power exercised by clinicians and medical institutions. This bio-power is ‘disciplinary’, in the sense that clinicians can influence patients to behave or identify in a certain way in response to illness (Gastaldo 1997, p.114; Lupton 1997, p.99; Press et al. 2000, p.239; Lyon 2007, p.84). Bio-power can be linked to medicalisation (see: Section 3.2.9), by which medicine seeps into social life and defines “normal and pathological” parameters (Gastaldo 1997, p.116), making health an ethical value which redefines the goals and projects pursued in private life (Rose 2006, p.25). Power practiced in this way is dependent upon the relationship between patient and clinician, in which the clinician’s training or expertise is acknowledged by the patient.

Medical power is not possessed by clinicians and institutions and exercised over patients by right for purposes of domination or political goals, but rather is created through ‘collusive’ medical relationships in which the patient, clinician and institution must each play its role in acknowledging the power of the other (Lupton 1997, p.100). What is missing from this account of bio-power is recognition of the power of patients beyond collusion—patients may argue for alternative treatments or actively resist the power of clinicians and institutions by refusing to follow ‘doctor’s orders’, or by not self-identifying as a patient. Ultimately, it is the patient that chooses to engage in a medical relationship with a particular clinician and institution. The power implicit in consent needs to be acknowledged, even where the patient is pressured by social norms and deference to expertise to behave in a certain way.

4.4.3.1.1 Risk Categorisation

PHM contributes to the bio-power of clinicians and medical institutions by contributing personal data through which categories can be created and assigned according to health condition, physiological parameters, familial history, genetic predisposition or future risk of illness, creating a basis for recommending treatments and behavioural interventions to benefit the health of the patient. Categories need not reflect actual health conditions currently inflicting the patient; in modern medicine, bio-power is often exercised by identifying patients 'at-risk' of a future affliction. As a form of social sorting, placing a patient into a risk category limits his future choices because such categories are "normalizing" (Clarke et al. 2003, p.173), meaning they are identities with certain characteristics into which patients are placed. Once there, patients can be treated as mere representations of a risk identity or manifestation of a disorder (cf. Lyon 2003; Monahan & Wall 2007; Light 2010). Monitoring data held in databases creates 'data doubles', or aggregates of personal data which, due to being made up of limited data from monitored parameters (and associated medical records), may fail to represent the socially embodied person the data is about (cf. Haggerty & Ericson 2000; Lyon 2007, p.55). These doubles are assigned to categories through which the user is identified as a certain type of person (van der Ploeg 2012, p.177), which affect how he is treated in the future by those with access to the data.

Following on from Foucault, Armstrong (1995, pp.400–1) sees modern medicine operating under the paradigm of 'surveillance medicine', in which people are more or less 'at-risk' of becoming ill rather than being seen as healthy, necessitating mitigation of risks through medical interventions and 'lifestyle' changes. For some, the rise of medicine as risk management eliminates the distinction between health and illness altogether, "since everything potentially is a source of 'risk' and everyone can be seen to be 'at risk'" (Petersen 1997, p.195). The extension of medical expertise or 'gaze' to all people is justified when citizens are viewed as "asymptotically or pre-symptotically ill" (Rose 2006, p.19). Whereas in the past risk calculations have been useful only for epidemiology at the population level, sorting patients by categories of risk has moved statistical probability of potential future illness into the realm of individual diagnosis (Press et al. 2000, p.241; Clarke et al. 2003, p.173). Without downplaying the epidemiological opportunities afforded by PHM data to identify new risk factors and links between behaviours and health (cf. Petersen 1997, p.197), the assertion that risk has replaced health and illness as measures of well-being is unconvincing. Ubiquitous surveillance would be required for all health concerns to be expressed in terms of risk. More

importantly, risk can only dominate medical discourses where patients are willing to participate in a medical relationship in which they are increasingly identified by characteristics of their body or family history placing them 'at-risk', undermining the potential for resistance and medical relationships directed by the patient's values.

4.4.3.1.2 Implications for User Identity

With that said, if PHM data can be used to identify health risks in users, it may influence users to increasingly view themselves as 'at-risk', affecting how they self-identify and behave.

Grouping patients by risk is intended to justify preventative medical interventions or lifestyle changes on the basis of characteristics such as age, weight, blood pressure and family history (Rose 2006, p.72). Being placed into a risk group can affect a patient's identity as if the predicted health condition had already occurred, changing how the patient behaves and is treated by others in an attempt to appear 'responsible' (Rose 2006, p.75). By creating opportunities to define new risk categories and place patients within them on the basis of monitoring data, PHM contributes to 'prepatient' identities, which are created, sustained and treated by health monitoring (cf. Rose 2006, p.94). These identities are lived out in social and medical relationships with family, friends, clinicians and medical institutions, each of which respond to the patient differently according to their perceived identity. Implications for identity were mentioned in the literature (see: Section 3.2.5), but the potential for PHM to contribute to the creation of new identities through risk categorisation was not mentioned.

4.4.3.1.2.1 *Biomedicalisation: From Clinical to Self-Care*

An increasing emphasis on risk in medicine (Armstrong 1995), which can be mitigated through lifestyle choices and behaving according to clinical recommendations, shifts the burden of health away from medical institutions and the state to the individual (Petersen 1997, p.194; Press et al. 2000, p.241). Risk management changes the goal of medicine from restoration of normality through clinical interventions to individual responsibility for the maintenance of health through mitigation of risks and self-governance (Clarke et al. 2003, p.165), revealing a desire for control over uncertainty central to risk as a concept (Press et al. 2000, p.242).

Throughout the twentieth century this type of "self-maintenance" was extolled as an ethical value of good citizenship in Europe and North America (Clarke et al. 2003, p.172; Rose 2006, p.22), according to which citizens can be identified as 'responsible' or 'good' as far as they pursue health through risk management (Petersen 1997, p.204; Clarke et al. 2003, p.172; Rose 2006, p.22). Relationships between patients, clinicians and medical institutions are changed as

self-maintenance increasingly shifts care away from face-to-face encounters to patients utilising techniques and technologies for self-care and self-monitoring (Clarke et al. 2003, p.165).

The promotion of personal responsibility for health is referred to as the biomedicalisation of life, by which individuals obtain “moral responsibilities [for health] to be fulfilled through improved access to knowledge, self-surveillance, prevention, risk assessment, the treatment of risk, and the consumption of appropriate self-help/biomedical goods and services” (Clarke et al. 2003, p.162). Whether PHM reinforces biomedicalisation and self-maintenance as an ethical value is dependent on the culture in which it is used. So far as PHM can contribute to the identification and mitigation of risk factors in patients, it can also support self-maintenance. It is therefore worth assessing in future deployments of PHM the extent to which it is used as part of an agenda of biomedicalisation, through which the burden of care is increasingly shifted to the patient and community by presenting usage as a moral responsibility.

4.4.3.1.3 Power Relationships

Biomedicalisation and the need for self-maintenance are reinforced by placing patients into risk categories and recommending self-care and lifestyle changes as mitigation techniques. The power to define risk categories therefore places great power into the hands of clinicians and medical institutions, but only if patients accept the categorisation and subsequent medical and lifestyle recommendations (cf. Lyon 2007, p.81). In medical relationships the perceived expertise of the clinician provides incentive for the patient to follow his recommendations. PHM causes a subtle but important shift in power in this regard; if defining categories or placing patients into categories is left to specialists or institutions with which the patient has not traditionally had a face-to-face relationship, a new stakeholder with the power to influence the patient’s behaviours and self-identification enters relationships mediated by PHM.

Even with such power for data custodians, surveillance is not distinctly beneficial or burdensome for service providers or users (Lyon 2001a, pp.136–7); sorting users into groups based on surveillance data, for example, can benefit users by directing them towards interventions perceived as helpful by service providers, while also burdening them by limiting choice to recommended treatments. For the provider, sorting facilitates management of

patient populations according to organisational norms (e.g. recommended interventions). However, when providers present adoption as a tradeoff (e.g. Lyon 2001a, p.136), in which it is necessary for users to shoulder the burdens of surveillance to receive its benefits, the opportunity for users to affect how surveillance is carried out, potentially reducing the burdens placed on patients in the pursuit of organisational norms (e.g. efficiency), is diminished. The 'ethical tradeoffs' seen in current discourse (see: Section 3.3.2) demonstrate that users hold a normative view of the technology shaped by the underlying power relationships with service providers.

4.4.3.1.4 The Need for Transparency

Operators possess significant power to change the behaviours and identity of surveillance subjects through social sorting, which enables profiling and discrimination according to norms reflecting the political values of custodians (Lyon 2007, p.183). For PHM, power may be seen in risk categorisation and care commissioning favouring specific patient populations. This power is often realised in closed off databases away from public scrutiny (Lyon 2007, p.181). One way to curtail this power is by guaranteeing patients access to PHM data held about them. However, knowledge of how the data is being used by data custodians is also necessary. Transparency is therefore needed regarding the process of defining new categories within PHM-linked databases, as well as the process of matching users to categories (cf. Lyon 2007, p.177). Categorisation can be seen as an ethical issue because categories define people in certain ways, affecting how they are treated by medical institutions and clinicians (cf. Lyon 2007, p.192). Monitored patients risk losing context-rich relationships with clinicians when medical care increasingly involves evaluation of fragmented data representations of patients, reducing opportunities to incorporate the patient's values and expectations into care.

4.4.4 Surveillance, Virtue and Colonisation

So how do colonisation, virtue ethics and theories of surveillance combine to create a conceptual framework to understand the moral potential of PHM? Some of the implications for colonisation in terms of virtue ethics were explored above (see: Section 4.3.5). The surveillance theories reviewed here contribute further insights relating to the effects of surveillance in descriptive terms, often hinting at ethical issues but lacking an ethical framework against which the power granted to medical institutions and service providers by PHM can be criticised. Conceptions of autonomy, human dignity, privacy and personhood may provide a basis for criticising surveillance of individuals, in the sense that personal freedoms

are curtailed through analysis of private data. Where these concepts fall short is in providing a basis for assessing the ethical implications of PHM for medicine as a practice, seen in medical relationships between clinicians, patients and medical institutions. Virtue ethics provides such a framework, meaning surveillance theory provides an explanation of how PHM may undermine the realisation of virtues and virtuous behaviour in medicine, damaging medicine as a practice and potentially harming patients.

Quantification and categorisation of patients through monitoring allows for remote assessment based on 'objective' data, even when used alongside a patient's verbal account in clinical encounters. In a system flooded by longitudinal data representing the health of a user, the need to see patients as socially embodied persons is reduced, limiting opportunities for virtuous behaviour in face-to-face encounters. The movement to 'abstract decision-making' can be seen as an 'institutionalisation' of medical practice, in the sense that institutions already manipulate data representations of patients to make decisions regarding care commissioning or the needs of patient populations; the better these decisions are made, in terms of efficiently meeting the needs of the patient, the more the institution sustains itself. The question can be asked, however, of whether this type of patient encounter undermines the ends of medicine for the sustenance of the institution when incorporated into the healing relationship (cf. MacIntyre 2007, p.194). If decisions about the patient can be made on monitoring data alone, justified through utilitarian appeals to a 'need' for efficiency, there is a risk of limiting opportunities for virtuous behaviour in the healing relationship, which can only be realised when clinicians are forced to encounter the socially embodied patient.³⁶ In such relationships, the patient is in a weaker position because his physical body is amenable to remote evaluation, from where the patient's values and expectations cannot influence the healing process. Social sorting based on PHM data allows for the substitution of the 'data double' (see: Section 4.4.3.1.1) in the healing relationship.

What is lost by the exit of the socially embodied patient is the opportunity for physicians to be compassionate and gain the trust of the patient, and to demonstrate their concern for the patient's interests. In facing the potential institutionalisation of, at the very least, chronic illness management, physicians may need to exercise integrity, justice, truthfulness and

³⁶ A similar rationalisation of decision-making, in which certain types of information are favoured at the cost of eliminating other information from view, can be seen in business intelligence. This idea is explored in an unpublished manuscript entitled "Virtue Ethics and Business Intelligence" by Neil McBride.

courage in reflexively rejecting certain forms of PHM which place too much space between physicians and patients, to be filled by other stakeholders and remote processes of data recording, analysis and recommendations.

The changes to the healing relationship seen from the perspectives of virtue ethics and surveillance theory can be understood as outcomes of the colonisation of the patient's lifeworld and clinical encounters by institutional values and expectations. As described previously colonisation occurs when PHM acts as a mediator in medical relationships between patients, physicians and institutions, including the healing relationship, by providing monitoring data and analysis of the patient's condition (see: Section 3.4.1.3). External expectations can be embedded in systems which recommend certain behaviours or provide information for self-assessment, changing how the patient views himself, his personal space and his condition. Colonisation brings with it many ethical implications for patients in terms of privacy, autonomy, safety and so on (see: Section 3.4.1.4). Virtue ethics as a theoretical framework helps make sense of the meaning of these implications for how medicine will be practiced, and how it should ideally be practiced against an ethical standard. It provides a basis for criticising the implications of PHM as something more than mere 'costs' of the perceived safety afforded by monitoring (see: Section 3.2.3). It also helps picture the technology as more than a mere extension of existing treatments, and instead as a medium for new models of care in which the values of institutions and clinicians play a greater role in the 'private' life of patients.

4.5 Conclusion

In this chapter a theoretical framework was developed based on virtue ethics, surveillance theory and colonisation of the lifeworld. The framework, developed to respond to the perceived need to ethically assess the implications of PHM for medical relationships identified in the previous chapter (see: Section 3.5), assists in understanding the moral potential of PHM. Virtue ethics provides a counterpoint to utilitarian support for PHM based solely on economic or cost-efficiency concerns, while grounding an account of the ethical acceptability of new medical interventions in the ends of medicine as a moral practice. Surveillance theory helps explain how PHM can be conceived of as surveillance, which changes how care is provided to patients by creating opportunities for categorisation and remote analysis. The alterations to the healing relationship identified as ethically problematic from the perspectives of virtue and

surveillance can be understood as examples of the colonisation of the patient's lifeworld by the concerns of the system, which travel through PHM in mediated care.

It is difficult to assess the explanatory power of the framework for specific applications without context-specific analysis, in which it can be seen how patients, practitioners and institutions perceive the changes brought about by PHM. As suggested above, ethical analysis should not be limited to theoretical analysis alone because issues occur in specific contexts of use and have implications for real people (see: Section 3.1.1). Anticipatory actions can be taken to correct problematic ethical issues, or to prevent future harm, but only when the implications of the technology for potential users (and other stakeholders) are understood. Recognising this, it would be helpful to study patient populations that are being targeted by PHM, to gain insight into the perceived ethical implications of PHM in terms of its effects on medical relationships.

Conflicts may be evident between the norms which patients, clinicians and medical paying organisations expect to govern PHM mediated care (see: Section 3.4.1.1). These norms are evident in attitudes towards PHM, including perceived benefits and problems with specific applications and uses of the technology and collected data. To see how these norms shape the ethical implications of PHM in particular contexts of use, empirical research into stakeholder attitudes within a particular context of use or healthcare system is appropriate. To begin to understand the context in such an empirical study which aims to address the third research question, an analysis of the strategic aims of that context's medical institution(s) must be conducted prior to assessing the attitudes of patients and practitioners. To this end the next chapter reviews England as a setting for such research, where PHM is seen by the National Health Service and Department of Health as a tool to drive down costs and shift care burdens to the community. Institutional values can be seen in strategic support for PHM, which may conflict with the moral obligations of practitioners and the expectations of patients.

5 Chapter 5: PHM in England

5.1 Introduction

Before PHM is adopted across healthcare services in the EU, the ethical implications of PHM mediating care should be investigated. Medical care occurs via relationships between institutions, clinicians and patients, which can be distinguished by characteristics of stakeholders, such as the medical needs of the patient, the training and values of the clinician, the structure and goals of institutions as well as the overall model of the healthcare system. The implications of PHM as a mediator will therefore depend upon the characteristics of the context in which a relationship occurs. As an example, different issues will be faced in privatised versus national systems: in the former, extensive restrictions on the transmission of PHM data to third parties may be necessary to prevent monitored individuals from being denied insurance or 'penalised' with higher premiums.

Empirical research into a specific context of use is therefore necessary to understand how the norms and contextual attributes governing medical relationships change how PHM and its ethical implications are experienced on a case-by-case basis. The point of such a study is not to solve a particular ethical dilemma in a particular context, but to understand the implications for relationships according to the experiences and perspectives of actual stakeholders. These implications may be comprehensible within the conceptual framework developed in Chapters 3 and 4, or parallel to themes in the discourse, but may also reveal new insights or implications. In general, empirical study will help demonstrate how the framework applies in a real context, and hopefully provide new insights which necessitate expansion or refinement of the framework.

As a result of their broad European focus, the two FP7 projects framing this research were unable to closely examine implications of PHM in a particular context or health system, such as England's National Health Service (see: Chapter 1). The National Health Service (NHS) provides an ideal context for empirical study due to its size and strategic support for implementing PHM across a variety of health services. With a responsibility for over 53 million citizens in England (Office for National Statistics 2012), the NHS is one of the largest national healthcare systems in the EU strategically supporting the implementation of PHM (see: Section 5.2). This support can be seen in strategic aims set by the Department of Health (DH) which encourage remote monitoring of chronically ill and elderly patients. Strategy is intended to 'trickle down' across

England through several levels of medical institutions, where aims are implemented by regional clinical commissioning groups (CCG), trusts and care institutions such as hospitals through care commissioning (or 'purchasing' medical services) and innovation adoption.

England also has a recognised shortage of care facilities and services for chronically ill and elderly patients (Department of Health 2011b; Department of Health 2012a; Campbell 2013a; Campbell 2013b), which creates a context in which PHM may be seen as a solution to provide care with reduced human interaction, outside of hospitals and care residences. PHM may also contribute to addressing the shortfall of professional carers for disabled individuals in England by which face-to-face care time is restricted (BBC News 2013; Leonard Cheshire Disability 2013); however, monitoring systems cannot replace the physical support provided by carers with daily tasks such as bathing, cooking or getting in/out of bed. Reductions such as these can be seen as a method of shifting the burden of care onto the community, while potentially providing replacement technologies to manage shortfalls of human workers or medical resources. The need for efficiency and resource savings potentially creates a conflict between utilitarian aims and the right to acceptable medical care (UN General Assembly 1948, sec.25), loosely defined as care which secures the health and well-being of the patient without imposing significant social or ethical burdens, for example by failing to respect the dignity, privacy, confidentiality and human rights of patients (The National Health Service 2013).

England also has a long history with surveillance; as a country with less than 1% of the world's population (Office for National Statistics 2012), it possesses 20% of the world's closed-circuit televisions (CCTV) as of 2007 (Lyon 2007, p.39). This unique familiarity with everyday surveillance provides another incentive to study England, as it may translate into increased acceptance of surveillance in a medical context, or alternatively reactions against the privacy implications of PHM through comparisons to CCTV.

As a site of empirical study, the NHS is a context in which medical relationships exist with the potential to be mediated by PHM. Assessing the prospects of NHS support of PHM allows for analysis of medical relationships against a background of institutional strategies and values driving diffusion of PHM, and the goals and predicted outcomes of its use. Some of the institutional values which may eventually colonise the patient's lifeworld can be seen first in strategic support for PHM.

5.2 Strategic Support of PHM in England

The reorganisation of the NHS under the Health and Social Care Act of 2012, along with changes to NHS information strategy (e.g. Department of Health 2011b; Department of Health 2012a), can be seen as a response to financial challenges and predicted demographic shifts towards an increasingly elderly population, which is predicted to increase the burden on healthcare resources in the future (House of Commons Health Committee 2005; Department of Health 2011b). Information and innovations in medical technologies and care are seen as the only way to meet these challenges (Department of Health 2011b), described as a “need” for “efficiency gains” while providing the same or better quality of care (Department of Health 2010a, p.11).³⁷ The gap between financial considerations and ‘best practice’ continues to shrink, as GPs and practice teams organised into GP consortia have taken over care commissioning budgets and responsibilities (Department of Health 2010a). Consortia and practitioners are held financially accountable on the basis of the quality of care provided, guaranteed through inspections, adherence to ‘best practice’ guidelines and provisioning of budgets to meet local needs (Department of Health 2010a, p.27). GPs will be responsible for the financial implications, or efficiency, of their practice, which is intended to encourage innovation and improved management of chronic illnesses and costly conditions.³⁸

PHM may contribute to meeting the information and financial needs of the NHS. Resources are “directed towards priorities” to meet the “almost unlimited demand” on a national health system with limited resources (Fitzgerald et al. 2002, p.1443). As a result, innovations in “non-priority areas,” or ones which create additional demands on resources may fail to be adopted (Fitzgerald et al. 2002, p.1443), regardless of clinical effectiveness. If PHM is linked with cost-effective chronic illness management, then this strategic aim may be achievable through

³⁷ ‘Efficiency’ is an unclear concept within the NHS strategy documents reviewed. The term appears to refer to attaining the maximum possible benefit in terms of quality of care while committing the least possible resources. Efficiency could therefore be increased by eliminating redundant bureaucratic processes, or replacing an existing treatment with one which provides ‘better’ health outcomes at the same or reduced cost. Defined this way, efficiency is a normative concept which relies upon the prescription of value to certain parameters to define desirable health outcomes. Accordingly, a treatment which is more expensive but ‘better’ for the patient, compared with existing practice, may be treated as an efficient use of resources despite the higher cost. Far from a precise concept, even a general ratio between financial cost and patient benefit for an intervention to be viewed as efficient is not clear in the reviewed documents.

³⁸ The distinction between ‘purchasers’ and ‘practitioners’ has been collapsed in the move towards GP consortia, suggesting that financial considerations or the ‘efficiency’ of particular treatments may increasingly influence care. This is not to say financial considerations directly influence treatments offered by practitioners to patients, but rather that practitioners are increasingly expected to adopt innovations and treatments in their practice which are seen as cost-effective at a commissioning level.

deployment of PHM, suggesting how PHM may be initially used by the NHS.³⁹ Strategy sets the stage for the rapid diffusion of innovations, such as PHM, which are believed to provide these benefits and equivalent care without raising costs.

In strategy (Department of Health 2011b; Department of Health 2012a), telehealth, telecare and PHM are seen as a way to utilise information to reduce the costs of chronic illness management and consumption of acute care services (Department of Health 2010b; Department of Health 2011a; Department of Health 2011b; Department of Health 2012a). Predicted efficiency gains focus on fewer and shorter hospital stays for the monitored, and a reduced need for residential care achieved through patients increasingly ageing in monitored homes (Sorell & Draper 2012, p.38). If chronic illness can increasingly be managed at home, hospital beds and resources available for acute care increase (Steventon et al. 2012). Support for PHM is seen in financial incentives for telehealth and telecare systems, and the recognition of the value and importance of health data for driving economic growth in England as well as research and development of innovations in the NHS (Department of Health 2010a, p.25; Department of Health 2011b). Telehealth and telecare are seen as a way to improve chronic disease management while reducing costs, with the aim of diffusing systems to three million users by 2016 (Department of Health 2011b, p.26; Department of Health 2012b). PHM is broadly seen as a tool to meet the increasing financial and care burdens placed on the NHS by utilising information to increase efficiency.

5.2.1 The Value of Information

Cost-effectiveness is not simply a comparison of the costs of providing different treatments or systems to patients. Under strategy, patient data is seen as a valuable commodity waiting to be exploited for gains in efficiency and quality of care (cf. Department of Health 2012a). In recent years the DH has committed to developing an information culture characterised by “openness, transparency and comparability” between patient information from diverse sources (Department of Health 2010b; Department of Health 2012a). Information has come to be viewed as a panacea to improve medical care and health outcomes, empower patients to control and make decisions about their health based on personal information, support

³⁹ The cost-effectiveness of PHM, and the ethical acceptability of introducing financial responsibility to practitioners, falls outside of the scope of the thesis. For more on the influence of ‘efficiency’ and financial constraints on clinical encounters, see Appendix 4.

England's economy, as well as drive research, innovation development and diffusion.⁴⁰ Cost-effectiveness must be understood as a measure of the value of innovations and information in these terms.

The value of information is a measure of its contribution towards future innovations, research and economic growth, and towards improving the efficiency and quality of care in medical practices. A prime example of the perceived value of information is the exploitation of patient data to support secondary strategic aims. Anonymised patient records will increasingly be made available to the private sector to drive future "system improvement, care choices, efficiency, integration, research, and growth" in the NHS (Department of Health 2012a).⁴¹ Leadership at all levels of the NHS have been called upon to support "efficient and effective" uses of information which "improve health care and outcomes." Specifically, data of interest will be linked across and between patient care records and used to "audit quality, improve services, **guide commissioning, and identify trends and patterns of health**" (Department of Health 2012a). An emphasis is placed on the prevention of ill health and the efficiency of NHS organisations and practices at a local level, which are intended to allow practitioners to prioritise face-to-face contact for the neediest patients, with other needs being met in the community (e.g. self-care, informal care, home visits from professionals) or via remote monitoring (see: Section 4.4.3.1.2.1). Information is said to help identify the most clinically effective treatments at a local and national level, and to match available resources with medical needs at a local level (Department of Health 2012a). A context is thus created in which PHM data can be used to expand the informational basis for commissioning and care decisions, by identifying health patterns and individual histories across local patient populations. It is unclear whether PHM data will be seen valuable in this regard, but information-centric strategy hints at the broader value of PHM beyond the immediate care of patients.

⁴⁰ The attitude taken towards information is overly optimistic and deterministic—information is seen as guaranteeing improved efficiency and the quality of care (cf. Fairweather & Rogerson 2001). The possibilities of overwhelming practitioners with information, or alienating patients through the new emphasis on self-responsibility and prevention are not considered, to name only two of the many possible negative outcomes of the increasing emphasis on information in the NHS.

⁴¹ The strategies are implemented by the Clinical Practice Research Datalink and the Open Data Institute (UK Cabinet Office 2011; Department of Health 2011b), which provide linkage services between "unidentifiable, individual level" health data to support research and innovation in the NHS and the private sector. Additionally, the Department of Health's Health and Social Care Information Centre will routinely publish aggregate national data sets of anonymised linked information to support research, innovation and the presentation of information to the public (Department of Health 2010b).

5.2.2 Secondary Uses of Patient Data

The value placed on patient information in strategy suggests that PHM creates new opportunities for ‘secondary uses’ of gathered data not directly related to the user’s care, such as grounding care commissioning decisions in the needs of local patient populations. Beyond internal administrative uses, health data is increasingly viewed as a valuable commodity to be traded with private sector organisations and individuals (Department of Health 2012a). Although the primary purpose of the NHS is to provide sufficient healthcare for England’s population, a secondary role is in encouraging economic growth, particularly in supporting research and the health and life sciences industry (Department of Health 2011b) which are seen as critical to meeting the increasing demands placed on the NHS by financial and demographic trends (Department of Health 2010a, p.24). Information is seen as the key to achieving these aims, which implies movement of patient information within and between the NHS, governmental bodies and the private sector, facilitated by the Health & Social Care Information Centre.

Existing ‘patient-identifiable information flows’⁴² are evidence of this connection, including exchanges concerning adverse drug reactions, patient drug abuse, care needs including nursing home accommodation, disease registers, toxicity of newly marketed pharmaceuticals, and various “referrals and reports to non-NHS agencies,” all of which are transmitted from NHS bodies to various government bodies (e.g. social services, child protection services) as well as various ‘private-sector’ bodies including the health services industry, care services (e.g. private care residences), academics and researchers (The Caldicott Committee 1997). Information flows change rapidly in step with reorganisation of NHS and governmental bodies and services, so these flows should not be considered an exhaustive list by any means. Although not based on existing practice and thus unable to identify where specific misuses of PHM data could occur, historical flows demonstrate that various pieces of patient-identifiable information are already transmitted for secondary uses and stored in a multitude of databases across NHS, governmental and non-governmental sites.⁴³ These types of information flows are examples

⁴² ‘Patient-identifiable information’ is defined as information on any of the following: Surname, Forename, Initials, Address, Postcode, Date of Birth, Other Dates (e.g. death, diagnosis), Sex, NHS Number, N.I. Number, Local Identifier (e.g. hospital or GP Practice Number), Ethnic Group, Soundex code, or Occupation. Any single piece of information from this list can potentially be used to infer the identity of the patient (The Caldicott Committee 1997, p.89).

⁴³ Despite repeated attempts to find further details regarding information flows and specific databases in which PHM data may be transmitted and stored, nothing was found beyond those offered in the 1997 report (The Caldicott Committee 1997). Without overreaching, this finding suggests that the internal

of ‘secondary uses’ of data, defined as any use of a patient’s data to achieve aims beyond the immediate care of the patient.

PHM has the potential to significantly increase the availability of longitudinal health data, in a sense opening up the lives and private behaviours of patients to commissioning, research and other secondary uses (cf. Section 4.4.3). The possibility of secondary uses of anonymised and aggregated health data negatively impacting on patients remains unacknowledged by the Department of Health (cf. UK Cabinet Office 2011, p.5), despite granting significant power and new data sets for medical institutions to assess and understand the health and behaviours of patient (see: Section 4.4.3.1). Longitudinal data enables the identification of health patterns, behaviours and risk factors. On this basis, secondary uses of PHM data may lead to a greater categorisation of local health populations by risk or health patterns (cf. Clarke et al. 2003; Lyon 2003), justifying further colonisation of the patient’s lifeworld, for example through monitoring or recommendations concerning newly identified personal health risks. While this can be seen as beneficial in the sense that categorisation may allow for more efficient health planning and commissioning, or for epidemiological research into disease factors and health patterns across monitored populations, the potential for monitoring data to change how patients, practitioners and other medical professionals interact should be assessed before PHM is widely adopted; however, this ideal timeline appears to be reversed in England.

5.3 Diffusion of PHM

The strategic support seen for PHM is intended to encourage diffusion across NHS services. Standards of evidence are typically required to demonstrate clinical efficacy and cost-effectiveness of any new innovation prior to diffusion, yet these standards are not apparently met as of yet with PHM. ‘Evidence-based medicine’ has been strategically adopted by the NHS in recent years to support the best possible medical innovations and care, often relying on guidelines published by the National Institute for Health and Clinical Excellence (NICE) to establish ‘best practice’ as guidance for care commissioning (Department of Health 2010a, p.8). Innovations with proven clinical and financial efficacy will become increasingly important in the near future, as new ways are sought to provide sufficient medical care under demographic and economic demands.

workings of the Health & Social Care Information Centre (and the Secondary Uses Service which it replaced in 2013) are not readily available to the public.

The push towards ‘evidence-based medicine’ (Department of Health 2010a, p.8) has changed how innovations are adopted within the NHS (Ferlie et al. 2005, p.118). At both local and organisational levels, practitioners and professionals have been encouraged to adopt innovations with empirically proven clinical efficacy in comparison to existing and alternative treatments (Fitzgerald et al. 2002, p.1431; Ferlie et al. 2005, p.118). Randomised clinical trials (RCT) are often seen as the ‘gold standard’ for evidence of clinical efficacy and cost effectiveness (Dudley 1986; Rosen & Mays 1998; Ferlie et al. 2005, p.130) in the “hierarchy of evidence” established under evidence-based medicine (Ferlie et al. 2005, p.130). For some innovations, guidelines are established by the NICE to guide ‘best practice’ or establish quality standards (Fitzgerald et al. 2002, p.1431). Innovations are intended to be judged against existing treatments in terms of clinical efficacy, costs and efficiency to determine best practice, although this approach risks minimising the importance of social and emotional aspects of health, such as physical touch, central to patient quality of life.

In practice, this approach requires “the same or better clinical effects should be achieved at equal or lower costs” for an innovation to replace an existing treatment (Rosen and Mays 1998, 104). Financial incentives will often accompany NICE Technology Appraisals⁴⁴ to motivate local adoption of specific innovations (Department of Health 2010a). The assumption of such top-down approaches is that clinical evidence is a reliable and clear guide to ‘best practice’, or that scientific evidence will objectively indicate the most effective innovations, regardless of specific contexts of use as well as organisational, clinical and patient needs. In practice, the assumptions behind this model of diffusion do not hold true; standards of evidence and ‘optimal’ solutions are not shared across medical professions,⁴⁵ meaning value-laden interpretation of bodies of ambiguous and contested evidence is required to identify ‘optimal’ innovations (Fitzgerald et al. 2002, p.1437), as opposed to a single, unified and objective body of evidence pushing diffusion.

⁴⁴ Technology Appraisals are evidence-based assessments of pharmaceuticals, treatments and medical technologies which typically rely upon randomised clinical trials. They are considered authoritative statements of ‘best practice’ by the NHS at a national level (Department of Health 2011b, p.15), although this does not necessarily translate into deferment to authority by local practitioners in judging evidence as credible and innovations as desirable.

⁴⁵ The relative ‘credibility’ of evidence differs between medical professionals and specialities, which differ in terms of background knowledge, training and approaches to care (Fitzgerald et al. 2002, p.1438). For example, results from RCTs are criticised due to a lack of generalizability between diverse contexts in which the innovation would be used, characterised by health professionals, patients and medical organisations with a diversity of needs and expectations (Rosen & Mays 1998, p.118).

Despite the alleged objectivity of diffusion, it has historically been politically malleable, with changes in “objectives, scope and emphasis” often mirroring changes in political power (Wainwright & Waring 2007, p.49). As it actually occurs, diffusion is a “slow, complex and contested” process, as dependent upon evidence of clinical- and cost-effectiveness as on local and organisational politics and relationships between professional bodies (Fitzgerald et al. 2002; Ferlie et al. 2005, p.123). Linear models of diffusion (cf. Rogers 2003) in which diffusion proceeds on a series of linear steps fail to capture reality, in which diffusion processes are “erratic, circular or abrupt...[and] may come to a full stop or go into reverse” (Ferlie et al. 2005). Diffusion in the NHS is a local process, occurring within specific organisational and professional bodies or practices such as CCGs, subject to various expectations of evidence as well as top-down strategic and financial pressure to adopt. The importance of this aspect of diffusion is in recognising that even though governmental strategy says that a technology or application will have effect X, Y and Z, the effects of PHM on medical professionals, practitioners and patients within specific contexts of use cannot be predicted deterministically at the technology-level. Top-down strategic support for PHM is therefore not a guarantee of local diffusion across the NHS.

5.3.1 Piloting PHM

The case of PHM diffusion is somewhat unique, in that the DH has gone beyond strategic support by conducting an extensive pilot study of telehealth and telecare technologies closely related to PHM in terms of technological capacities and aims (e.g. Philips 2013). In contrast to PHM the piloted technologies require patient interaction to take readings, answer questions and transmit data, although the general aim of remotely monitoring patients remains comparable. Although not equivalent to PHM, piloting of such systems can be seen as further evidence of the DH’s desire to encourage broad adoption of PHM and related technologies in the near future. The Whole System Demonstrator (WSD) programme consisted of a RCT in which over 3200 patients with COPD, heart failure or diabetes mellitus were provided with telehealth or telecare systems, or assigned to a control group receiving normal care (Department of Health 2011a). The size and scope of the study was intended to assess the potential and implications of diffusing telehealth and telecare across England among a variety of local healthcare organisations, meaning that the WSD can provide an evidence-base for the DH’s telehealth and telecare diffusion strategy going forward.

Numerous secondary analyses of cost-effectiveness, psychological effects, quality of life, hospital admissions, mortality and other health outcomes of the WSD have been carried out, with results still forthcoming. Available results are limited to telehealth, and indicate a mixture of outcomes: telehealth was shown to be more expensive than existing care and thus not cost-effective (Henderson et al. 2013). Telehealth also lowered emergency hospital admission rates, mortality and length of hospital stays for users compared to the control group (Steventon et al. 2012). Reductions in emergency admissions⁴⁶ have been mirrored in other non-WSD piloting for COPD patients (Lomas 2009; Ure et al. 2012), albeit with concomitant increased utilisation of other care resources, including telephone contact with professionals (e.g. nurses) managing the system and hospital/outpatient admissions.

Effects of telehealth on quality of life were less clearly positive in the WSD and related studies. Participants in a secondary study of the WSD surveyed via questionnaire indicated that telehealth did not make a difference in terms of quality of life and psychological effects compared with “usual care,” suggesting that claims that telehealth improves health-related quality of life for COPD patients are unfounded. This finding is reinforced by three systematic reviews of the effects of telehealth on quality of life—two for COPD and one for diabetes. In recognition of the ambivalence of current evidence, and the lack of research connecting quality of life to ethical implications including surveillance implications and “undermining of the traditional (face-to-face) therapeutic relationship” (Cartwright et al. 2013), further research is needed into the effects of telehealth in general and the WSD in particular in terms of the experiences of patients in these terms.⁴⁷

The need for such research is reinforced by another secondary study of individuals who withdrew or decided not to participate in the WSD, which provided insight into the link between social and ethical effects of telehealth and quality of life. Reinforcing themes found in the discourse above (see: Section 3.2), respondents associated telehealth with dependency and illness, and sought to distance themselves from negative connotations of ageing by self-identifying as too healthy, young or independent to use the systems. Telehealth was believed to undermine existing methods of care, taking away the sense of control, independence and personal responsibility associated with self-care. Medicalisation was also a factor (see: Section

⁴⁶ Telehealth and telecare are thought to reduce ‘just-in-case’ hospital admissions by creating an alternative contact method with practitioners (House of Commons Health Committee 2005, p.7).

⁴⁷ The latter study quantitatively measured QALYs via a questionnaire, which may be an overly simplistic method to evaluate quality of life (cf. Edgar 1997; Edgar 1998).

3.2.9), as some respondents did not want to be reminded of their health or worry about the implications of readings taken by the systems. Going forward, it was recommended that systems be tailored to specific contexts of use, and for the views of potential users and carers related to identity, independence and autonomy to be accounted for in developing and diffusing the systems (Sanders et al. 2012). Although the study was concerned with barriers to adoption, it stopped short of assessing the implications of user and carer views from an ethical perspective, which raises the question of whether it is morally acceptable for the DH to advocate the diffusion of telecare and telehealth systems while implications for user identity, independence and autonomy are not yet understood from the perspective of users in the WSD.

Despite full results of (secondary analyses of) the WSD being unknown at the time (Department of Health 2011a), the DH pushed in 2011 to diffuse telehealth and telecare throughout the country as a means to reduce emergency hospital admissions, mortality and the length of hospital stays on the basis of limited 'headline' results (Department of Health 2011a; Department of Health 2011b, p.26). Telehealth and telecare are being supported to improve chronic disease management while reducing costs, with the aim of diffusing systems to three million individuals with social or home care needs, including those with diabetes mellitus and (potentially) dementia, by 2016 as part of the 'Three Million Lives' campaign (Department of Health 2011b, p.26; Department of Health 2012b). This enthusiasm contradicts results from the WSD (published after 2011) which only show a reduction in usage of hospital resources and mortality for telehealth, with WSD evidence for telecare still not available to date. The lack of evidence for claims of cost-savings is supported by a 2007 systematic review of international clinical (60) and observational (30) trials involving telecare (Barlow et al. 2007), which concluded that cost-effectiveness varies according to context of use and specific telecare innovations, without a clear trend which would indicate telecare is a cost-effective alternative to existing care. On this basis it is clear that, despite lacking the standard of evidence enshrined in 'evidence-based medicine', the DH has pushed forward with its plan to diffuse telehealth and telecare across the NHS.

The early push for telehealth and telecare is indicative of the influence of politics in the diffusion of innovations in the NHS, as the Department does not cite a background body of clinical trials or other evidence of clinical efficacy, cost-effectiveness and social, emotional and psychological outcomes for patients and providers, despite supposedly modelling diffusion of

new innovations in the NHS on ‘evidence-based medicine’ (Department of Health 2010a, p.8). The push for telehealth and telecare is, however, not a new phenomenon; the DH has been advocating adoption since 2004 with Preventative Technology Grants intended to support local development of telecare programmes (Department of Health 2004; Department of Health 2005). At this time telehealth and telecare were viewed as a means to “bring substantial benefits in providing people with greater choice over their care, assisting people to remain in their homes, reducing inappropriate admissions, facilitating discharge from hospital, and providing advance warning of deterioration in a patient’s condition” (Department of Health 2004, p.68). A later report by the House of Commons Health Committee (2005) noted the Department’s apparent lack of awareness of challenges accompanying telehealth and telecare, including the loss of human contact resulting from remote care and the greater burden placed on informal carers at home (cf. Palm 2011). The WSD goes some way towards rectifying the apparent lack of evidence. Despite this, the push to diffuse telehealth and telecare on a wide scale while simultaneously lacking a significant body of supporting evidence appears to be motivated not by evidence, but rather by strategic and political aims.

5.4 Shifting Values in Medical Relationships in England

The politically-motivated diffusion of PHM, perhaps fuelled by perceived resource shortfalls in coming years (e.g. Campbell 2013a; Campbell 2013b), indicates how institutional values and goals influence the delivery of care in England. Strategy suggests that the mode of care for cohorts of patients will increasingly be modelled around efficiency, enacted through the adoption of PHM and similar technologies. Long-term care and management of chronic illnesses are intended to increasingly involve remote monitoring of conditions at home, reducing instances of face-to-face encounters with practitioners (Department of Health 2011b, p.27). Chronic illness management will increasingly take place not in physical spaces and encounters with practitioners, but in the transfer, storage and analysis of digital information, or remotely monitoring the patient for unexpected or undesirable parameters. Telehealth and telecare are seen as a way to reduce ‘inappropriate’ face-to-face medical encounters with lower cost alternatives, with every 1% of reduction predicted to save up to £200 million (Department of Health 2011b, p.27).⁴⁸ Although not mentioned in these forecasts, institutional values can be seen in the strategic framework into which telehealth and telecare fit, which involves not only increasing patient participation in medical decision-making, but

⁴⁸ How this figure was calculated, and whether it is an annual or one-off savings, was not explained in the report. The concept of ‘inappropriate’ encounters was also not defined in the report.

also shifting a greater burden for medical care onto patients themselves. It is worth noting, however, that institutional and clinical values can align in evaluating the effects of PHM—a reduction in face-to-face visits may free up the time of clinicians to prioritise patients with the greatest need, or reduce the amount of time spent travelling to care for homebound patients.

5.4.1 The Influence of Institutional Values on Care

The diffusion of technological innovations intended to meet changing demographic and economic burdens are simultaneously changing the relationships between patients, doctors and medical organisations (Lupiáñez-Villanueva et al. 2010). Recent years have seen the “rise of managerialism, centralised control and an assault on, or an erosion of, power of the medical profession” in the NHS (Wainwright & Waring 2007, p.50), endemic of a morally problematic disregard for the central virtues or professionalism which characterises medicine as a practice and social good (cf. Pellegrino 2002; MacIntyre 2007). Medicine in the NHS is becoming increasingly bureaucratic as a practice (Wainwright & Waring 2007), in the sense that efficiency and cost-effectiveness are deemed equally important as providing high quality care (Department of Health 2011b). Although the former may be necessary to achieve the latter in a healthcare system characterised by increasing demand, bureaucratic ideals risk eclipsing values and virtues of ‘good’ or clinically sufficient medical practice, defined in isolation of resource constraints. The shift to GP consortia may be seen as a fix for the perceived rise of managerialism; however, the increasing emphasis on efficiency and remote care suggests that the practice-internal norms by which good medical practice is defined are at risk (see: Section 4.3.2.1).

The strategic outlook of the NHS emphasises efficiency, in the sense that “processes” which no longer “add value” should be eliminated in patient care through innovations which provide the same or better care to the patient at equal or lower costs (Department of Health 2011b, p.8). While it is easy to take this language merely as a call to eliminate redundant bureaucracy, it raises a question over the ‘goods’ valued in the care encounter by the DH. If, for example, PHM enables the treatment of a greater number of patients remotely at the same cost as existing face-to-face clinical practice or care encounters in the home, are the latter seen as processes which no longer add value? There is a risk of reducing the needs addressed in care encounters to merely biomedical parameters, ignoring the social and emotional needs met through human care (see: Section 3.2.6) as well as the physician’s duty to physically examine the patient when necessary (General Medical Council 2013).

The bureaucratisation of care in the NHS signals a change in the relationship between patients/clinicians engaged in clinical encounters and medical institutions, by which the options available for long-term care are increasingly limited or guided by institutional strategy. If remote monitoring is seen as a cost-effective alternative to existing care, as suggested by DH support, then it would appear that clinical practice is being controlled to some degree by values set 'from above'; PHM is strategically seen as a 'best practice' innovation, considered apart from its social and ethical 'costs' for patients.

5.4.1.1 Shared Decision-Making

One such 'cost' is the influence of institutional values on relationships between patients and clinicians, which are set to move towards a model of shared decision-making in which patients are increasingly 'empowered' by the right to access care records and affect care decisions. A central component of the new approach to information is the principle of 'no decision about me without me', by which patients are entitled to transparent access to their care record, and can choose with whom and when it is shared (Department of Health 2010c, p.22).

Technologies which enable information sharing and patient access are seen as a way to move towards a patient-provider relationship characterised by shared-decision making (Department of Health 2012a), which is claimed to improve health outcomes, satisfaction with care, management of chronic illnesses and adherence to treatments among patients, while potentially delivering cost-savings. The principle reflects a shift of power in the reorganisation of the NHS under the Health and Social Care Act of 2012, according to which the NHS and healthcare are becoming increasingly 'patient-centric', with patients being given more "information, choice and control over how their care is delivered" (Department of Health 2010c, p.17). The involvement of patients in clinical decision-making is seen as a way to improve the quality of care and clinical outcomes delivered by the NHS (Department of Health 2010c, p.18), which implies that a paternalistic model of the patient-provider relationship is deficient in comparison (cf. Emanuel & Emanuel 1992; Kaba & Sooriakumaran 2007).⁴⁹

In a shared decision-making relationship, the patient is increasingly seen as personally responsible for the maintenance of health (Kaba & Sooriakumaran 2007), with implied duties

⁴⁹ The view that shared decision-making inevitably delivers better outcomes for all patients is problematic, as it relies upon the patient's ability to understand information, make rational decisions based upon it, and to decide upon appropriate recipients of their care record. Problems associated with the strategic shift towards shared decision-making are beyond the scope of the thesis. For criticisms of the shared decision-making model of care described in NHS strategy, see: Appendix 5.

for self-monitoring and self-care to free up medical resources for those with urgent acute needs (see: Section 4.4.3.1.2.1). In other words, NHS restructuring in the face of demographic trends shifts burdens which were previously fulfilled by medical institutions onto individual patients and the community. The responsibility which accompanies increased power for patients is (unsurprisingly) not acknowledged at the strategy level, but is central to understanding how relationships between patients and providers are shifting, mediated by PHM.

5.4.1.2 Towards Self-Responsibility and Self-Care

In exchange for increased access to care records and decision-making power under the ‘no decision’ principle, the patient is expected to adhere to treatment programmes and accept responsibility for their choices, including lifestyle (Department of Health 2010a, p.16).⁵⁰ Although not explicitly stated in this position, the language of ‘personal responsibility’ suggests that limitations may be placed on the care that patients can expect to receive in the future from the NHS on the basis of the lifestyle and medical care they choose.

A shift towards community and self-care is not necessarily problematic if the predicted benefits of a patient-centric care strategy come true. Still, the community and individuals are implicitly expected to fill the gaps created by shared decision-making and a reduction in face-to-face clinical encounters (cf. Department of Health 2011b). Gaps include the increasing need for family members and friends to provide ‘informal care’ for dependent individuals at home (cf. Palm 2011), or for patient support groups to assist patients in understanding their care records (e.g. Department of Health 2010a, p.15). New medical relationships are created between the patient, family members and the community, the burdens of which are not insignificant. Informal care already accounts for a significant portion of care in England, where it is estimated that 36% of the £23 billion total costs associated with dementia in 2012 came from informal care inputs (Alzheimer’s Society 2012). The financial burdens attached to informal care can be significant, with carers often having to cut back hours or stop working altogether (Palm 2011), resulting in an estimated £690 million in lost wages and £123 million in lost tax revenue in 2012 alone (Alzheimer’s Society 2012).

⁵⁰ It should not be taken for granted that patients want or require access to care records or greater decision-making power in the healing relationship. While some patients will certainly desire greater access and responsibility, such as those preferring medical relationships modelled on the ‘informative’ or ‘deliberative’ model (Emanuel & Emanuel 1992), adapting the overall care strategy to this subset of patients conflicts with the expectations of users preferring a paternalistic model of care, or those preferring ‘happy ignorance’ (see: Section 9.3.1.1).

Informal care is merely one example of the implications of the NHS increasing the burdens placed on individuals and the community for adequate medical care. PHM is seen as a method to shift care (and decision-making power) to the community in the name of efficiency and 'increased quality of care' (cf. Department of Health 2012a) by acting as a 'watchful mediator' between clinicians and patients.

5.4.1.3 Mediation of Relationships and Duties of Good Medical Practice

The shift in care values evident in NHS strategy may change the duties of physicians in England in terms of 'good' medical practice. Many of the medical virtues described previously (see: Section 4.3.3) are evident in codes of practice governing medical professionals in England, including the General Medical Council's guidance emphasising physician competency, honesty, trustworthiness, integrity, compassion, concern for the safety and rights of patients to privacy and dignity, as necessary components of good medical practice (General Medical Council 2013, p.4) and continued trust in medicine as a profession (General Medical Council 2013, p.21). The patient must be treated as a socially embodied individual, "taking account of their history (including the symptoms and psychological, spiritual I, social and cultural factor), their views and values" (General Medical Council 2013, p.07). Importantly, these characteristics are not conceived of as virtues of good practice, but rather duties of the physician to patients and other members of the profession (General Medical Council 2013, pp.4–5).

The treatment of medical ends as duties to patients, rather than virtues of the physician, means an official responsibility to resist the corrupting influence of institutional values in medicine does not exist for physicians in England. These values come to colonise practice and the patient's lifeworld through PHM (see: Section 3.4.1.3). The conclusion can be reached then that the values governing medical relationships in England may be changed by PHM. A virtue-based account (see: Section 4.3) helps explain how these changes occur, and how physicians and patients may resist colonisation through (demanding) virtuous behaviour. Virtues place the physician's character as a defence against the institutional erosion of the profession, or practice (cf. MacIntyre 2007, p.194). Duties defined by institutions necessarily incorporate goods external to medicine, without which the survival of the institution cannot be guaranteed. The indication from this assessment of strategy is that the external goods which UK medical institutions are concerned with, chief among which is efficiency gains to reduce costs of care, may increasingly influence patient care, seen through the implementation of PHM in medical relationships. In response, systems or strategy may need to change to ensure

the ends of medicine are fully met, and patients receive adequate care focusing not only on physiological parameters measured at a distance, but their complete set of values and needs as socially embodied individuals with physical and mental health and well-being.

5.4.2 Conclusions

Shifts in NHS strategy reflect how the model of medical care is changing in England. PHM can be seen as a tool which makes these changes possible. The DH has predicted changes to how care is delivered, such as reduction of face-to-face encounters and the formation of new caring relationships in the community. The purpose of reviewing strategic support was not to criticise the ethical acceptability of the strategy itself, but rather to understand how PHM fits into strategy, and to identify the types of medical relationships which will be enabled and changed by PHM in England. Institutional values which may come into conflict with patient and clinician norms of 'good' medical care were also identified in strategy. Overall, the DH has broadly ignored the ethical and social implications of introducing PHM, such as the transformation of the home into a 'virtual hospital' and changes to medical relationships and social relationships (see: Section 3.2.9), as demonstrated by the lack of an ethical component in the WSD. This failure to incorporate ethical reflection in strategy further supports the need for a conceptual framework for the evaluation of emerging PHM applications.

A possible explanation for the lack of concern shown by the DH to the ethical implications of PHM is that the issues of importance to the DH in justifying medical strategy and associated technologies are limited to a very narrow range of political and economic concerns, particularly clinical efficacy and cost-effectiveness, through which the quality of care may be quantitatively assessed in terms of patients treated or hospital beds available. It may therefore be necessary to create a 'feedback loop' to broaden the concerns of those responsible for diffusion by introducing the perspectives of 'ethical experts' and potential users of the technology, assessed through empirical study. The inclusion of ethical expertise and lay perspectives in such a feedback loop ensures that both theoretical and pragmatic ethical perspectives are accounted for in analysis. This is not to suggest a new formal arrangement for governance and strategic thinking is necessary, but rather that research providing such perspectives which responds to the limitations seen in strategy is necessary (cf. Shaw & Stahl 2011). The research undertaken in this project can be understood as one possible way (among many) of beginning to address this gap.

DH strategy can be traced to demographic predictions which have spurred perceived need for and development of technological solutions to problems that may not actually occur in the future. For this reason the demographic predictions (United Nations 2007; United Nations 2008; Population Reference Bureau 2012) and perceived benefits of monitoring patients at home (Neild et al. 2004; Gaul & Ziefle 2009; Bowes et al. 2011; Palm 2011; Ure et al. 2012) which motivate support for PHM among developers and politicians (OECD 2010; Garcia-Morchon et al. 2011) should not remain unchallenged. PHM may fail to prove cost-efficient or safe, for example if an influx of health monitoring data increases the burden placed on health professionals (cf. Percival & Hanson 2006, p.901; Ure et al. 2012), potentially causing 'information overload' (Himma 2007). Monitoring data and systems found confusing by users may increase the demands placed on carers and call centres responsible for overseeing PHM programmes (Ure et al. 2012), fuelling rising costs. Beyond this, advances in medical science in the coming decades may delay expensive health expenditures towards the end of life, or create increasingly healthy ageing populations with increased economic and social output (Palm 2011; Arrison 2011), which cannot be accounted for in the demographic forecasts that are often considered in isolation without awareness of advances in other fields (Palm 2011) upon which this claim depends.

The ethical implications of PHM need to be understood as distinct from the accuracy of demographic predictions and perceived healthcare shortages. While such shortages would certainly weigh heavily in a utilitarian calculus for distributing insufficient healthcare resources, the ethical implications of the technology itself should be understood apart from its economic effects (see: Section 4.2). For instance, imagine that PHM is shown to provide a cheaper method of caring for elderly at home, thus allowing for a greater number of patients to receive care than would otherwise be possible. While the utilitarian might argue that this fact provides a moral reason to use PHM, this line of reasoning does not explain how PHM will affect the quality of care experienced by the user. It is in this sense that demographic predictions are only a secondary concern in the ethical analysis of PHM—the technology itself can imply benefits and burdens for users, healthcare professionals and medical institutions beyond the scope of cost-benefit analyses. What requires further discussion, then, is the impact of PHM apart from its perceived economic benefits and burdens. It may be revealed, for example, that PHM offers improved outcomes over all aspects of traditional treatments. It should thus not be assumed that PHM implies an ethical tradeoff for users, by which users are expected to carry certain burdens for the benefit of the system (see: Section 3.3.2), until the

ethical implications of the technology are identified and compared with existing medical practice. On the other hand, appeals to economic benefits of PHM in response to shifting demographics should not be taken as a compelling reason or ‘trump card’ for diffusion of the technology, unless a purely utilitarian approach is taken.⁵¹ The danger of relying upon demographic predictions to dictate ethically acceptable behaviour lies in overshadowing other, non-economic implications of the technology.

5.5 Research Question

The uncertainty of demographic predictions hints at the difficulties of ethical assessment of emerging technologies. PHM is a new way of delivering medical care, complementary to the strategic movement towards shared-decision making, self-care and self-responsibility.

Uncertainty prevails over how PHM will contribute to norms of ‘good’ healthcare and the changing values of patients, clinicians and medical institutions in this regard. With widespread institutional support for PHM and strategic movement towards a model of care in which the community and patients are expected to shoulder a greater burden in terms of self-care and informal care of dependents (cf. Williams 2002, p.142), England offers an ideal site for study in which uncertainty can be reduced through ethical analysis informed by healthcare strategy.

To move forward with the research and to answer the third research question posed above (see: Section 3.5.1), a methodology capable of assessing an emerging medical technology under conditions of uncertainty, which can unite theoretical and empirical perspectives, is necessary. This need gives rise to the final research question addressed in this project:

What methodology is capable of capturing and incorporating the moral beliefs of potential users of an emerging medical technology (such as PHM) into ethical analysis?

This question requires answering in the context of the proposed empirical study, which aims to improve and refine the conceptual framework, and explore its explanatory power for implications perceived to arise in particular contexts of use, based on insights from targeted patient populations. The framework is based on the connections between virtue ethics,

⁵¹ Indications of the influence of utilitarian calculations on the restructuring of the NHS have been noted by (Tyler 2007). Utilitarian arguments may provide a compelling reason to accept ‘ethical burdens’ of PHM (see: Section 4.2). With that said, under many forms of utilitarianism appeals to economic benefits do not act as a ‘trump card’ (cf. Singer 1993; Mill 2002), suggesting the sort of economic calculus described in relation to the NHS is, at best, a very simplified form of utilitarianism.

surveillance theories and colonisation as a response to utility-based support (see: Section 4.4.4). As argued above (see: Section 3.4 and Chapter 4), these theories can help explain the moral potential of PHM. This position does not mean other ethical and social theories are incapable of 'making sense' of PHM, but merely that these three theories are seen as helpful and have not yet been explored in PHM ethics discourse (see: Chapter 3). The conceptual framework built from these theories, then, is intended to further PHM ethics discourse by introducing a new theoretical perspective which identifies unrecognised issues and provides a new perspective concerning the values and actions at stake when addressing the ethical implications of PHM.

To test the framework the empirical study needs to examine the expectations of patients in a healing relationship with providers when care is mediated by PHM, revealing norms evident in their expectations of care, virtues which patients expect physicians to possess, or new concepts to improve the framework's ability to explain the effects of PHM on the healing relationship and the institution's place in it. The test of explanatory power will be to comprehend the responses of potential users in terms of colonisation, virtue and surveillance and identify new ways in which colonisation presents an ethical risk to stakeholders and medicine as a practice that cannot be explained from these perspectives. This is not to say analysis will be limited to these three theories, but rather that one of the explicit goals of the analysis is to 'test' whether viewing the data through these theoretical lenses helps identify or explain the values at stake in ethical issues associated with PHM. In this way necessary refinements and limitations of the framework can be identified.

5.6 Conclusion and Research Questions

In this chapter evidence has been presented to explain the strategic context into which PHM will be introduced in England. This context is characterised by strategic support for related technologies such as telecare and telehealth, despite unproven clinical efficacy. By understanding the motivations behind support for PHM, insight is gained into how PHM may initially be deployed in England and whether the expectations of potential users and clinicians in this context conflict with institutional strategy. The chapter has thus provided a necessary backdrop to answer the third research question concerning the ethical implications of PHM for medical relationships.

Chapter 5 marks the conclusion of the first half of the thesis. The remaining five chapters discuss methodological and epistemological issues, before describing and presenting the results and recommendations of an empirical study with potential users of PHM. The first half was concerned with defining the scope of the research project, in part through defining PHM and reviewing ethical implications of the technology seen in academic discourse. The scope of the research project has been defined through four research questions posed above:

- 1. How can PHM be defined?**
- 2. How can PHM be categorised to link potential ethical implications to specific emerging applications?**
- 3. What ethical considerations will arise when PHM is introduced into relationships between patients, clinicians and medical paying organisations?**
- 4. What methodology is capable of capturing and incorporating the moral beliefs of potential users of an emerging medical technology (such as PHM) into ethical analysis?**

With the scope of the project defined, research questions 1 and 2 answered (see: Chapter 2), and research question 3 beginning to be addressed (see: Chapters 3, 4 and 5), the next two chapters aim to answer research question 4. Methodological and epistemological considerations necessary to meet the requirements of research question 4 are reviewed, in the process creating a methodology capable of contributing to answering research question 3. A main component of the answer to question 3 posed thus far is the conceptual framework. As of yet the explanatory power of the framework has not been tested in connection to specific PHM applications or contexts of use. Therefore, to strengthen the conceptual answer to question 3, it must be shown how the created methodology can lead to empirical research amenable to exploring its explanatory power, identifying its limitations and suggesting necessary refinements.

To succeed in refining the conceptual framework in this way through empirical study, the methodology must allow for in-depth discourse into the implications of PHM for medical relationships, through which the power of the framework to explain the perspectives of potential users can be explored. As PHM is an emerging technology, the methodology must also be designed in such a way that uncertain normative claims about the future based on past experiences can be considered credible. Finally, as the primary aim of the study is refinement and expansion of the conceptual framework, the methodology needs to enable the

combination of empirical and theoretical claims in an approach to ethical analysis. A methodology meeting these requirements is detailed over the following two chapters.

6 Chapter 6: Hermeneutics and Empirical Methodology

6.1 Research Methodology

A methodology is required to capture and assess user attitudes towards the potential ethical implications of PHM, understood in terms of effects on medical and social relationships. As an emerging technology the methodology must be amenable to future-orientated research, allowing for engagement of potential users of PHM. To begin to understand the methodological challenges presented by ethically assessing an emerging technology, an exploration of philosophical paradigms which inform empirical research is required.

All research is guided by basic beliefs about the organisation of the world. These beliefs, also called a paradigm or interpretive framework, determine how a researcher views the world and influences the empirical questions he asks about it (Denzin & Lincoln 2000, p.19). Paradigms encompass basic epistemological, ontological and axiological commitments, all of which guide the actions of researchers and affect the relationships found in the world (Denzin and Lincoln 2000, 157; Lincoln and Guba 1994, 105; Patterson and Williams 2002). All paradigms rest on foundational assumptions about the 'true' epistemic and ontological nature of reality.

Six philosophical paradigms can immediately be identified which can ground social research: positivism, postpositivism, interpretivism, hermeneutics, critical theory, and constructivism (Lincoln & Guba 2000, p.168; Schwandt 2000). Qualitative and quantitative methods of empirical research are initially plausible in all of these paradigms. Each is considered below regarding suitability for studying an emerging technology, which necessitates developing understand of potential futures.

6.1.1 Positivism

Positivism rests on the objectivist ontological assumption (sometimes called realism) that an external reality governed by "immutable natural laws and mechanisms" exists that can be examined by researchers (Huber 1995; Denzin & Lincoln 2000, p.9; Denzin 2001, p.21). The natural world is seen to exist separately from humans, meaning it is orderly and amenable to 'objective' empirical observation (Kuhn 1970; Oates 2006). The province of positivistic qualitative research is the intersection of this world with the lived experiences (e.g. beliefs and actions) of individuals. However, this province does not endorse the creation of reality, knowledge or meaning through individual interpretation, meaning positivism conflicts with

constructivist paradigms (e.g. interpretivism, hermeneutics) (Denzin & Lincoln 2000, p.8). The belief in an external reality also necessitates the elimination of bias by keeping the researcher external from the phenomena studied. Where researcher influence or 'bias' is detected, it may invalidate results. Positivist research strives towards the creation and testing theories generalisable across contexts which explain "the way things are" or how external reality operates through causal relationships (Lincoln & Guba 1994, p.109). Only findings which can be replicated are 'true', representing the desire for objectivity in methods and results (Lincoln & Guba 1994, p.110). As much as possible experiments are designed to isolate 'confounding' influences to reduce bias, even though these influences are part of the context in which a phenomenon occurs and can thus help explain it.

6.1.1.1 Criticisms of Positivism, Objectivity, and Objectivist Ontologies

Positivism has historically led to causal explanations of phenomena through observation. The credibility of the process is linked to the objectivity of the method, in which existing phenomena can be observed and measured; studies are repeatable in this sense. Objectivity is undermined by the interdependency of facts and theories, meaning facts only have meaning when viewed through a theoretical lens. Under the positivistic definition of objectivity, "hypotheses must be stated in ways that are independent of the way in which the facts needed to test them are collected," so if facts only having meaning within a theoretical framework, they cannot objectively validate hypotheses (Lincoln & Guba 1994, p.107). 'Objective' facts are often value-laden (Molewijk et al. 2003), comprehensible only from the perspective of a particular theory or paradigm—the phenomenon observed is observed *as* something. Objectivity therefore fails as a measurement of credibility in positivistic social research because the act of observation implies interpretation.

Objectivity has also faced a problem of induction, referring to the claim that objective truth cannot be discovered by induction. Theories cannot be created or verified through induction using a set of facts, as facts can be applicable to multiple theories, meaning 'bias' enters induction through the researcher choosing to explore or build a particular theory. Attempts at the "discovery" of objective theory through induction, such as Strauss and Corbin's Grounded Theory(s) (Strauss & Corbin 1994), would appear to fail in their search of systematic methods to describe objective truths. As long as theories can only be falsified (as demonstrated through Popper's observation that one cannot prove that all swans are white, only that the

existence of a black swan proves that all swans are not white) (Popper 1959), positivism can never arrive at universal truths via induction.

For studying the future, a fundamental problem exists for positivism in social research.

Positivistic inquiry can only observe phenomena known to the researcher in the present—the future cannot be foreseen, meaning observation is impossible. Future occurrences can only be engaged through the claims of potential users of the technology, meaning understanding is developed through understanding the motivations and meaning behind the attitudes or normative claims of potential users. If the technology does not yet exist, or is not yet used by the participants in a study, the researcher can only rely on open-ended questions posed to potential users which explore attitudes towards potential uses. An empirically observable phenomenon does not exist, meaning positivism is incapable of studying the future implications of an emerging technology—the only source of data, pre-user attitudes, would be understood as a ‘confounding influence’ on causal explanations. Furthermore, any resolution of this difficulty would collapse positivism into interpretivism because attitudes towards non-existent phenomenon are social constructions without an associated observable phenomenon.

As a result of these criticisms, positivism, objectivity and objectivist ontologies which are limited to the existence of an external social reality are inappropriate for studying an emerging technology. Although attempts have been made to rescue positivism in social empirical research (e.g. postpositivism) (Wildemuth 1993; Fischer 1998), the above criticisms can never be fully overcome by any paradigm that embraces an objectivist ontology based around empirically observable phenomena. Constructivist ontologies, which posit the existence of a social reality built and interpreted through human interaction (see: Section 6.1.3.1), may provide a way forward. According to such an approach, attempts to understand social empirical data without acknowledgment of social and historical context result in incomplete understanding of the phenomenon. It follows from this position that assessment of PHM necessitates engagement with and understanding of the social context in which PHM will be used.

6.1.2 Interpretivism

In contrast to the positivistic pursuit of objective truth, interpretivism is focused on non-causal understanding of human action. To interpretivists, human action is inherently meaningful, meaning the intention behind it defines the kind of action it is, and that the action can only be

understood by accessing the system of beliefs and meanings in which it is formed (Outhwaite 1975; Schwandt 2000, p.191). To understand the content of a particular action, the researcher must interpret the intentions of the actor (Schwandt 2000, p.191). Most interpretive approaches share these assumptions and a qualitative approach to research (Denzin & Lincoln 2000, p.10; Schwandt 2000, p.189), but differ in methods of correctly interpreting the content of an action (cf. Schwandt 2000, p.192). Interpretivist approaches to research are united by the claim that human subjectivity or intention is a central component to knowledge.

Interpretivist approaches can be divided into 'objectivist' and 'subjectivist' approaches according to the ontological position taken on the researcher's ability to reconstruct the *original* meaning and intentions of actions. Objectivist approaches claim intentions can be expressed in objective terms by an outsider that interprets and reconstructs the original meaning of the actions of others (Lincoln & Guba 1994, p.114; Schwandt 2000), whereas subjectivist approaches claim that understanding is unavoidably filtered through an individual's perspective constituted by his unique history and values, meaning complete understanding of the perspectives, values and meaning attached to an action by others is impossible (cf. Gadamer 1976a; Widdershoven 2005). This belief can be seen in references to taking the perspective of 'others' in ethnographic studies or interpreting interviews (Eisenhart 1988; Walsham 1995; Atkinson & Hammersley 2007). The reconstruction of the views of others is treated as the original meaning of the action (Schwandt 2000, p.192), despite the researcher being external to the action or original utterance (Garson 2006; Atkinson & Hammersley 2007). This is not to say that the researcher is unaffected by the phenomenon, but rather that the researcher's interpretation is attempting to reconstruct the phenomenon within the perspectives, values and background of others.

6.1.2.1 Criticisms of Objectivist Interpretivism and Detached Observers

Objectivist interpretivism may be rejected if the act of reconstruction is seen as inherently flawed, in the sense that the meaning and intentions the researcher 'sees' in an act or utterance are his own, and not identical to the subjective position of the actor. The possibility of reconstruction is based on the claim that the observer can act externally to, or not influence or be influenced by, the phenomenon. The researcher interprets the object of study within the context in which it occurs, discovering the original meaning and intentions attached to the object. The researcher does not influence and is not affected by the phenomenon, thereby remaining external to it (Denzin 2001, p.74; Casterlé et al. 2011, p.234). In this sense

understanding is seen as a process in which an outsider gains knowledge about a phenomenon.

This approach does not allow for claim that studying a phenomenon inevitably involves interpretation and interaction with it as a necessary component of developing understanding. Rather, interpretation is seen as an object-oriented art that can be judged by the degree to which an observer remains separated from the actor and context during the process of interpretation (Bernstein, 1983). Objectivist interpretivism can therefore be criticised on the same grounds as positivism as both operate within an objectivist ontology; in the same way that scientific facts pre-suppose particular axioms or theoretical frameworks in which a phenomenon is seen *as* something, so too does the interpretivist researcher view the phenomenon and actions of others through his unique perspective, built upon his personal background, values and training (cf. Olson 1986, p.161; Patterson & Williams 2002, p.22). This is not to say that the researcher cannot try to take the view of others, but rather that even when doing so the researcher cannot escape his personal background through which understanding of the phenomenon develops—interpreting the utterances of an actor as evidence that the actor holds a particular value which the researcher must adopt to interpret his actions, for example, is itself an act of interpretation. Beyond this, the researcher can never fully ‘become’ the actor, or internalise his unique history as his own because meaning is developed through the lens of history, culture and experience (Patterson & Williams 2002, p.23)—without sharing an identical background with the actor in these terms, the researcher can never interpret and understand the phenomenon in the same way.

Even if the notion of a ‘detached observer’ is seen as valid, pragmatic reasons exist to reject an objectivist interpretivist approach to research. As an emerging technology claims can only be made about potential uses of PHM, which are not based on past experiences with the technology. Given that such claims are based upon potential futures, and therefore inherently uncertain, critical assessment of the structure, logic, assumptions and supporting evidence of the claim is necessary to understand how far a claim is based on a realistic picture of the future, meaning one supported by recent technological development, strategy or planning. As these claims are prescriptive, or made about ethical implications of the technology, the moral values grounding the claim also need to be understood. These two components of ethical assessment of an emerging technology means a method of data collection is necessary between the researcher and actor to clarify these points. It is difficult to see how this type of

critical assessment could be carried out as a 'detached observer', unaffected by and not affecting the phenomenon under study; it would seem the researcher will necessarily have to probe, question and criticise the actor's claims because only the actor can explain their foundation or underlying reasoning. The possibility of detachment in such a dialogue is impossible—the researcher's questions and probes inevitably influence the actor's claims (cf. Widdershoven 2005).

If these criticisms are valid, sufficient reason exists to reject objectivist interpretivism. 'Subjectivist' interpretivist approaches, chief among which is hermeneutics⁵³, may offer an approach better suited to the challenges of assessing an emerging technology.

6.1.3 Hermeneutics

Hermeneutics is concerned with interpretation and meaning (Myers 2004, p.103), which differs from positivism and objectivist interpretivism in its ontological and epistemological commitments (Patterson & Williams 2002, pp.2, 9). Although originally a method of interpreting texts, hermeneutics has been adapted to the social sciences for the study of social phenomena (Bauman 1978) through interpretation of various 'texts' (Myers 1995, p.56) including interview transcripts, audio recordings, videos, documents and observations, among others.

Hermeneutics emphasises developing understanding through contextual interpretation of phenomena and human action, with due regard to the phenomenon's unique place in a social and historical context. The meaning of a phenomenon or action is grounded in "human experience...[as] a process of seeking understanding" through interpretation (Widdershoven, 2005, p.58, my brackets). It stands in opposition to objectivist hypothesis testing and 'bracketing' methods which remove phenomena from context (Patterson & Williams 2002, p.30), emphasising a person's prior knowledge as the foundation on which the meaning of a phenomenon is built (Addison 1989, p.52). Bracketing denies the fundamental nature of understanding (Patterson & Williams 2002, p.23), in which all understanding starts with reference to what is already known, which is then refined through consideration of further

⁵³ Hermeneutics has been subsumed under the interpretivist categorisation of paradigms by social researchers (Schwandt 2000), yet in acknowledging that "all human existence is hermeneutic in essence," proponents of hermeneutics correctly identify it as the underlying paradigm of all interpretivist approaches to research (Butler 1998, p.298; Klein & Myers 1999; Myers 2004, p.105). Whether hermeneutics is the foundation of interpretivism, or interpretivism the foundation of hermeneutics, is a matter of debate. While the debate has historical significance, its outcome is irrelevant to choosing a research paradigm fitting with the particular needs of the research project.

evidence, phenomena and beliefs. Hermeneutics seeks **contextual understanding** as opposed to **authoritative explanations** of texts and phenomena (Kinsella 2006). The inherent ambiguity of human interpretation and social interactions are central features of hermeneutics (Kinsella 2006). Conclusive explanations consisting of causal relationships are not sought; rather, understanding or the “interpretation of meaning” is the goal (Bauman 1978; Butler 1998, p.286). This is not to say hermeneutics lacks a systematic approach to understanding social phenomena:

"Rather, when properly conducted, [hermeneutics] is an empirical enterprise characterised by critical and 'meaningful' thought beginning with a particular perspective (the forestructure of understanding) progressing through a rigorous and systematic cyclical analysis (the hermeneutic circle) in which interpretations are evaluated and modified on the basis of the data that is then presented as evidence of the warrants for conclusions. Thus, when properly conducted, hermeneutic research...is empirically grounded, subject to external critical appraisal, and is systematic and rigorous rather than selective in its analysis of data" (Patterson & Williams 2002, p.36).

Hermeneutics thus provides a systematic, iterative and context-sensitive approach to understanding human interaction and the creation of meaning, which can provide insight into moral problems arising from social phenomena. The focus on human interpretation means it can be easily adapted to ethical assessment of emerging technologies, although the likelihood of interpretations matching actual future occurrences is undercut by the inherent uncertainty of future phenomena, or the inability to experience and interpret them first hand. Despite this, related existing practices provide a frame of reference through which uncertain normative claims can be passed; for example, experience with CCTV could lead a potential user of PHM to reject the technology based on privacy concerns and data sharing. Hermeneutics therefore provides a paradigm through which the claims of potential users of a technology about the technology can be seen as initially credible, or based on related experiences (e.g. prior use of medical recording/testing devices, management of a chronic illness), while recommending in-depth dialogue with stakeholders to developing understanding and question their perspectives (see: Section 6.1.3.3). On this basis hermeneutics is the preferred paradigm for the empirical study.

Before the study can be designed, the ontological and epistemological details of hermeneutics need to be explored in greater detail so a study design can be chosen which is compatible with hermeneutics as a paradigm. Categorisations of hermeneutics often divide the field into sub-

disciplines, by author, normative commitments, or field (Butler 1998, p.286; Patterson & Williams 2002, p.9). The approach described here most closely resembles the hermeneutics of Hans-Georg Gadamer (2004) applied within the context of social research in information systems (Bauman 1978; Butler 1998). This “antifoundationalist” version of hermeneutics has been acknowledged as the most suitable version in information systems research (Butler 1998, p.287), and empirically based ethical assessment (van Thiel & van Delden 2001; Widdershoven & Abma 2007; Widdershoven & van der Scheer 2008). Gadamer’s hermeneutics differentiates itself from other disciplines through ontological commitments that acknowledge the unavoidable subjectivity of interpretation, by which the possibility of ‘external’ or ‘objective’ interpretations of texts or phenomena, achieved by stepping out of one’s frame of reference (or hermeneutic circle), is seen as impossible.⁵⁴

6.1.3.1 *Ontological Commitments*

From an ontological perspective, Gadamer’s hermeneutics supports a constructivist view of reality, a narrative view of human experience, and a meaning-based view of human nature (Patterson & Williams 2002, p.14). According to this, humans both inhabit and create reality through interpretation, and give meaning to their experiences through the development of narratives and understanding. Humans are not seen as rational, analytical information processors inhabiting an external, objective world—while external structure does exist as a sort of ‘situatedness’ in which experiences occur and are interpreted (Malpas 2013), multiple social realities are created, interpreted, and given meaning by humans within particular social and historical contexts subjectively understood by each interpreter. Empirical research needs to account for this ontological position, with the implication that a prerequisite of understanding is exploration of context and the participants’ background frame of reference.

While interpreted and given meaning by humans, reality is not purely a human construction, instead created through interaction between individual consciousness and the structure of the world. The world is “co-constituted” by individuals and the world (Patterson & Williams 2002, p.14), meaning that experiences occur within a “situatedness” (Malpas 2013) or external structure which is not created through social interactions. Co-constitution should not be taken as dualism—the stance that an internal (consciousness) and external (structure) world exist independently of each other. Rather, the two exist in a “mutually defining inter-relationship,”

⁵⁴ The hermeneutic circle refers to the “whole” in which a “part” takes place, meaning the “intentions, beliefs, and desires or the text, institutional context, practice, form of life, language game and so on” in which a “specific sentence, utterance, or act” occurs (Schwandt 2000, p.193).

in which individuals orient themselves to a world which reveals itself to the individual (Patterson & Williams 2002, p.14; Malpas 2013). Another way of expressing this relationship is through "intentionality," or the recognition that consciousness can only be conceived of when it has an object; conscious beings are 'aware of' something. Structure exists beyond the reality created in social interaction, but the interpretation and meaning of both will be unique to individuals. The structure cannot be understood or described outside of the various meanings given to it through interpretation, so describing it as an 'objective' external reality is inappropriate—the meaning of the structure is created through interpretation, and does not precede humans encountering it.⁵⁵

An epistemic implication of this ontology is that meaning cannot be created or completely understood outside a particular frame of reference, made up of experiences, cultural membership, value systems and other influences on subjective interpretation. Phenomena do not therefore have universal meaning, shared among individuals within a particular context or society. Meaning and interpretation are historically and socially situated—removing either from the context in which they occur hinders understanding (Patterson & Williams 2002, p.24) (e.g. Sections 3.3.4 and 4.3.1.2). This position does not equate to the moral relativism sometimes associated with hermeneutics (cf. Habermas 1993; Edgar 2002, p.61) because it only requires meaning to be contextually situated—it says nothing of the relative credibility or truth of different interpretations (see: Section 6.3.1).

6.1.3.1.1 Predictions of the Future and the Possibility of Hermeneutic Dialogue

Co-constitution has implications for how the future can be reasonably studied. Individual phenomena can produce multiple valid interpretations across a diversity of people, each with a unique set of prior knowledge, values and experiences. Similarities can (and likely will) exist across their interpretations, especially within cultures and practices, because reality has structure shared between interpreters and experiences. The existence of a structure for reality implies that a reasonable, albeit contextually interpreted basis exists for future-oriented

⁵⁵ An example of co-constitution is the role of language in the creation of meaning. Concepts and phrases are not always perfectly translatable from one language to another, which leads to a loss of meaning. An example is Heidegger's concept of "Gestell," which cannot be perfectly translated into English. The original meaning can only be understood by members of the context (or culture) in which it was created; in this case, a non-German researcher would struggle to understand the meaning of the concept as defined by the culture that created it, without native fluency in the language. The researcher's meaning, based on his interpretation of the concept within his own frame of reference, would therefore be different than the (original) cultural meaning. In this case the concept and the culture which shapes meaning of the concept, both the 'correct' original meaning and the imperfect translation, are the structure given meaning by humans.

research. The structure of a future phenomenon can be predicted, although the accuracy of such predictions remains unknown until the phenomenon comes into existence. Within the context of emerging technologies, examination of the technological characteristics and aims of developing technologies; cultural, social and economic trends; and (potential) user expectations of the technology can provide insight into how the technology will be (initially) used and understood. Foresight and future studies, as well as other approaches to ethical assessment of emerging technologies (cf. Brey 2011; Stahl 2011; Stahl et al. 2010; Cagnin et al. 2008; Grunwald 2009) attempt exactly this kind of foresight, while realising that all such predictions are necessarily uncertain. If technological forecasting and foresight research can provide accurate predictions of the future, as determined by their own standards of accuracy (Stahl 2011b), then it follows that descriptions of the future derived from these sorts of studies can serve as the basis for a hermeneutic dialogue in which the future is assessed.

6.1.3.1.2 Human Experience, Meaning and Understanding as a Social Process

Human experience or decision-making are 'situated' in the sense that they occur within the external structure of the world and the meaningful actions of others towards them. Within the empirical study this ontological dimension of human experience is important to consider in the sense that the researcher needs to explore the restrictions placed upon the interpretations of the participant by their current social context (e.g. being a patient with diabetes mellitus). A parallel can be found with critical hermeneutics (Habermas 1975; Klein & Huynh 2004), and its focus on social structures and power relationships which influence interpretation and self-identity.

The focus on the participant's frame of reference and understanding of (potential implications of) the technology facilitates understanding the rationale of his attitudes towards PHM. With interpretation being affected by the actions of others, the role of the researcher in influencing others during study must also be recognised.

As understanding develops through interaction, neither the participant nor researcher's interpretation takes precedence in hermeneutics research—both contribute to understanding the phenomenon through unique perspectives. The researcher is able to provide an alternative frame of reference in dialogue, providing a basis against which the interpretations of others can be challenged and mutual understanding created through dialogue. To see how understanding develops through the encounter between actor and researcher, and why such a

process is a legitimate way of developing knowledge about reality, an exploration of the epistemological commitments of hermeneutics is necessary.

6.1.3.2 Epistemological Commitments

The epistemological commitments of hermeneutics relate to the nature of knowledge, and the process by which it is created. Interpretation is the first step towards understanding and knowledge by attempting to “bring to light underlying coherence or sense” (Taylor 1976, p.153) of actions or a phenomenon. Interpretation is based upon preconceptions, which leads people to view the same situation differently (Gadamer 2004). People emphasise different aspects of the situation, while ignoring others. Through this deliberate categorisation, situations are viewed “as something” (Widdershoven 2005, p.64). Interpretation is analogous with the concept of a narrative, in the sense that both emphasise features of the phenomenon which are seen as relevant or important, at the cost of downplaying other features (Kinsella 2006), to reveal the meaning or importance of the phenomenon. Interpretation is thus an attempt to “make sense of” something unfamiliar, to reflexively place it within one’s preconceptions and come to understand it.

Interpretation and understanding are the basis of knowledge. Interpretation relies upon the interpreter’s frame of reference, or prior knowledge and past experiences which shapes the interpretation of confounding experiences (Gadamer 2004; Myers 2004, p.109). Interpretation of a phenomenon can only occur if the interpreter has prior understanding of it (Widdershoven 2005), or a basis at which the interpretation starts. Prior understanding is expressed as prejudices, or an initial explanation or judgment of a phenomenon based upon past experiences, prior knowledge and expectations (Gadamer 1976a, p.240). Prejudices allow for the connection of events in a situation to the interpreter’s prior experiences, leading to interpretation and understanding. Prejudices must be reflexively and critically examined in the face of unfamiliar phenomena to determine the prejudice’s truth (Widdershoven 2005, p.59) and to develop understanding of the phenomenon which confounds prejudices.

Openness to other perspectives is a precondition to the development of understanding (Widdershoven 2005, p.65), because different perspectives highlight different aspects of the phenomenon. Interpretation can be understood as a process through which certain aspects of phenomena are highlighted or ignored according to the prior knowledge of the interpreter. Viewed as a necessity of understanding, reflexivity fosters development of knowledge, in

which inappropriate or inaccurate prejudices and unsupported beliefs are eliminated.

Addressing the gap between prejudices and confounding phenomena creates new understanding or knowledge. The creation of the new framework in this gap, informed as it is by prejudices, is the explicit process of hermeneutic understanding (Winograd & Flores 1986, p.32). However, prejudices are never totally open to reflection (both to the self and others), meaning the existence of a variety of perspectives and ambiguity are preconditions of understanding. As a result, understanding is never complete (Widdershoven 2005, p.57). The role of prejudices in understanding is illuminated in the comparison of methods of decision-making employed by humans; prejudices are the initial reactions which guide daily behaviour as opposed to slower, goal-oriented reasoning guided by evidence.

Understanding and openness, prejudices and new perspectives clash in encountering unfamiliar phenomena, which explains the difficulty of interpreting or researching potential futures (see: Section 7.3.1.1). The encounter is described by Heidegger as the difference between 'ready-to-hand' and 'present-at-hand' phenomena (Heidegger 1967; Butler 1998, p.289). Phenomena which are 'ready-to-hand' are not readily noticed and become 'second nature', or are seen as familiar and perfectly understood. Events which challenge the actor's understanding of the phenomenon break down the 'ready-to-hand' designation, requiring a reinterpretation of the phenomenon through consideration of alternative perspectives or horizons, if comprehension and understanding of the phenomenon are to be achieved. The phenomenon becomes unfamiliar or 'present-at-hand,' requiring reinterpretation within the actor's forestructure of understanding (Heidegger 1967), which is historically and temporally located. Reinterpretation (or initial interpretation of an unfamiliar phenomenon) tests the legitimacy of the actor's forestructure of understanding, transforming it as necessary to repair the "damage" caused by the 'present-at-hand' phenomenon (Heidegger 1967; Butler 1998, p.289). In all of this prejudices provide initial understanding of the unfamiliar phenomenon, which is then challenged and revised until familiarity is re-established.

Considering these factors, open-ended data collection and analysis methods which do not "narrowly predetermine the nature of responses" through rigid methodological standards are therefore consistent with the epistemological commitments of hermeneutics (Patterson & Williams 2002, p.39), which requires open-mindedness for the development of understanding (see: Section 6.1.3.2).

6.1.3.2.1 Fusion of Horizons

The fusion of the perspectives of actor and researcher to create a new understanding of a phenomenon reducible to neither perspective alone, for example through dialogue, is known as a 'fusion of horizons' (Butler 1998, p.289). In this sense a "horizon" is the understanding or interpretation of a phenomenon which is produced by the reflexive interaction between the interpreter's prejudices and the 'present-at-hand' phenomenon (Kinsella 2006). Fusion occurs within a dialogue, in which both participants are open to each other's perspectives and revision of their own horizon and forestructure of understanding (Gadamer 1976a, p.269). For qualitative research based on dialogue, the success of the dialogue can be assessed in terms of whether a fusion of horizons, or the emergence of new understanding, occurred.

The completion of a single dialogue resulting in a fusion is not the end-point of hermeneutics research, however. As with all knowledge in hermeneutics, a fusion creates provisional, context-specific understanding. Provisional understanding undergoes further testing and reinterpretation as new phenomena and perspectives are encountered. This process is known as the hermeneutic circle, and is a central concept in the iterative development of hermeneutic knowledge through research.

6.1.3.2.2 Hermeneutic Circle as a Metaphor for Research

The hermeneutic circle is a metaphor used to convey many aspects of the hermeneutics research process. At its broadest, the hermeneutic circle refers to an "inter-relationship between the part and the whole" (Patterson & Williams 2002, p.26). Phenomena are said to have multiple parts which are given meaning through comprehension of the phenomenon as a whole, "while at the same time the understanding of the whole is shaped by the parts" (Gadamer 1976a, p.117; Patterson & Williams 2002, p.26; Myers 2004, p.107). As the meaning of the parts is comprehended, the phenomenon must be iteratively reassessed in light of the new meaning. In encountering the phenomenon, the interpreter intuitively understands or anticipates the whole, and then closely interprets the parts to develop his understanding (Butler 1998, p.290). The parts and whole are interpreted in an endless series of concentric circles, which incorporate new perspectives, evidence and phenomena as understanding develops. The hermeneutic circle is an inescapable part of human understanding, meaning that "every interpretation relies on other interpretations" (Kinsella 2006). This ontological condition explains the impossibility of achieving objectivity in perspective, or completely escaping one's prejudices to take the perspective of another (cf. Schwandt 2000).

In contrast to other paradigms, hermeneutics research does not contain a finite endpoint such as theoretical saturation (cf. Strauss & Corbin 1994). Rather, given the subjective, changing nature of reality over time, represented in individualised interpretations of phenomena, static conclusions about (social) reality remain elusively out of reach (Patterson & Williams 2002, p.27). If research is viewed as a hermeneutic circle, in which (scientific) conclusions are reliant upon ever changing cultural, historical and technological understanding, then an open-ended approach is the only appropriate option which adheres to the ontological commitments of hermeneutics (Widdershoven 2005, p.65). While open-endedness may appear to imply a lack of rigour, the illustration of empirical research as a hermeneutic circle demonstrates its iterative, critical approach to analysis, in which the researcher's preconceptions are not given *a priori* legitimacy over the data. A related criticism is that temporary understanding implies relativism, for example in moral decision-making—how can a norm be criticised if any criticism is necessarily provisional and open to new interpretation or evidence? Such a criticism would however be unfounded—provisional understanding only implies that criticism and weighting of values in ethical analysis need to be revisited as the phenomenon about which a decision is made changes over time, while saying nothing of the quality or normative force of the claim itself. The hermeneutic circle is best understood as a description of the structure of dialogue (or moral deliberation) and the refinement of understanding over time, implying a need for open-ended reflexivity, rather than as an argument that all knowledge is inherently relative and therefore incapable of justifying prescriptive claims or actions.

Hermeneutic understanding implies that no research methodology can provide universal and permanent understanding of a phenomenon. However, hermeneutics can develop understanding far enough to provide justification for human actions and mutual understanding between stakeholders which facilitates cooperative living, and the resolution of competing normative claims. It is this aspect of hermeneutics which qualifies it as an effective paradigm for future-oriented research. Contextually situated provisional understanding of potential futures requires iteration to remain relevant, and cannot be understood as static predictions of an objective reality. While hermeneutic foresight provides initial understanding useful for developing anticipatory actions, it must be recognised that understanding necessitates iteration to justifiably ground responses to the perceived problems of emerging technologies.

6.1.3.2.3 Validity of Claims

Hermeneutics has been criticised for leading to political and moral relativism; the impossibility of escaping preconceptions in interpreting phenomena means that universal understanding or moral judgments are equally impossible. Moral judgments would instead be mere subjective expressions of culturally-informed values (Edgar 2002, p.61). As a form of emotivist moral deliberation, hermeneutics lacks a way to criticise interpretations as more or less credible.

This criticism is limited in the sense that the hermeneutic circle metaphor makes clear that understanding does not flow directly from preconceptions; rather, 'present-at-hand' phenomena and perspectives are encountered as understanding develops, meaning a conflict is setup between preconceptions and clashing perspectives, perhaps held by members of different cultures. The resolution of this conflict requires some form of deliberation to reach a new understanding, which is where relativism can be escaped by the need to justify decisions made in deliberation. A critical component—the need to judge interpretations as more or less credible—is therefore introduced, although a method for deliberation in this respect is not yet clear. On this basis the criticism may be successful in undermining the ability to reach justified moral decisions (for example) through a hermeneutic methodology. However, the success of the criticism in terms of moral justification (Edgar 2002, p.61) does not undermine the hermeneutic account of human understanding, interpretation and the formation of knowledge, its appropriateness as a model for (non-deliberative) empirical study, and for the need to account for characteristics of specific social and historical contexts in developing understanding.

Following on from this, the fact that all social agents can in principle interpret any social action suggests that all influences on the meaning of the action are apparent to interpreters (Habermas 1988, pp.171–5). Critical hermeneutics and critical theory contradict this claim, saying that power relations and ideologies are hidden in much social action which, until revealed, cannot factor into the interpretation of social actors. As a result, without a means for emancipation through revealing underlying causal forces on social actions, hermeneutics presents a problematic method for understanding social actions and phenomena.

This criticism may be unfounded. While claimed as a unique feature of critical disciplines, the need to distinguish between 'true' and 'false' prejudices is acknowledged by Gadamer (Gadamer 1976b, p.124). While objective grounds for resolving moral disagreements do not

exist in hermeneutics, the possibility of judging interpretations as more or less credible exists, although the method for doing so remains unclear. As suggested above, deliberation in this sense can be understood as a type of dialogue in which a fusion of horizons is sought, or new understanding through evaluating interpretations as more or less credible.

6.1.3.3 *Hermeneutic Dialogue*

Understanding cannot be derived uncritically from prejudices based on their past credibility. Rather, they require reconsideration and revision in the context of newly encountered phenomena and perspectives. Gadamer advocated dialogue as a tool for the development of understanding (2004), through which the credibility of claims can be evaluated. Understanding develops in step with consideration of new or unfamiliar interpretations and evidence. Hermeneutic dialogue aims to develop understanding through the fusion of horizons of actors with disparate backgrounds, personal experiences and cultural reference points.

6.1.3.3.1 Truth and the Ideal of Rational Discourse

Conceived as the search for understanding, dialogue provides justification for actions through “reciprocal acceptance of norms which will eventually guide the behaviour of negotiating partners.” Hermeneutics is concerned with providing rational arguments for human behaviour, also called “norms of conduct” (Bauman 1978, p.241) or *moral truth*.⁵⁶ Truth acts as a guiding principle for structuring communication between humans, allowing for consensus on correct interpretations of phenomena. Truth therefore provides justification for action.⁵⁷ What is so far missing from this account of hermeneutics is an approach, perhaps a set of criteria, through which the truth of interpretations can be evaluated. For this piece of the epistemic puzzle, an appeal must be made to the critical philosophy of Jürgen Habermas.

An account of truth arrived at through communication is given in Habermas’ Theory of Communicative Action (TCA) and seen initially in the ‘ideal speech situation’ (Habermas 1984; Habermas 1985) (see: Sections 6.1.3.3.1 and 7.3.2). According to the TCA human beings as social entities need to communicate in order to survive and prosper. Humans have a range of possibilities of communicating, with communicative action being the best or most highly

⁵⁶ Truth is moral in the sense that it is a normative claim—it provides justification for human action. It is contrasted with absolute truths, or statements about which we are certain. Deductive reasoning may be capable of reaching absolute truths (Hume 1978).

⁵⁷ For an explanation of how truth acts as a guiding principle for cooperative life and justified actions, see: Appendix 6.

developed. Whenever human beings communicate a set of validity claims arise: truth (Wahrheit), rightness (Richtigkeit) and authenticity (Wahrhaftigkeit). Communicative action requires the speaker to engage in a discourse whenever any of these validity claims are queried, meaning communication has broken down. This implies a willingness to engage with the interlocutor, to take her seriously and to be willing to change one's positions in the light of that argument (Habermas 1997).⁵⁸

The TCA identifies standards which must be met in discourse for its outcomes to be considered true, or as justification for action. Rational discourse is dialogue in which:

“Validity claims of assertions, recommendations, or warnings are the exclusive object of discussion; that participants, themes and contributions are not restricted except with reference to the goal of testing the validity claims in questions; that no force except the better argument is exercised; and that, as a result, all motives except that of the cooperative search for truth are excluded” (Habermas 1975, pp.107–8).

The process requires that all stakeholders affected by the discourse be involved (or at least given the opportunity), which guarantees that all “alleged interests” are considered in discourse regardless of the relative power or social status of participants—the only relevant “power” in rational discourse is that of the strength of arguments (Bauman 1978, p.242), as judged by its participants. Resulting intersubjective agreement provides “normative status” or credibility to the “*common* interests” of the participants, because the interests were agreed upon in a process that precludes deception. Interests are seen as common “because the constraint-free consensus permits only what *all* can want” (Habermas 1975, p.108). Rational discourse is free of deception because the values or “interpretations of needs” of individuals are transparently discussed and refined in the discourse—the process thus leads to the refinement of individually held interpretations of personal needs through dialogue with other stakeholders (Habermas 1975, p.108). In such a process, only those claims which can be communicated to other stakeholders in an intelligible way, which depend upon a shared cultural background or prior knowledge for comprehension, will find a place in intersubjective agreement. Such claims will therefore represent “*generalisable* interests,” or those which can be “*communicatively shared*” and are found rational, convincing or otherwise in agreement with the developing interpretations of other stakeholders in the dialogue (Habermas 1975, p.108). Rational discourse is thus meant as a process which will arrive at consensus resembling

⁵⁸ Part of this paragraph is taken from a manuscript currently under review for publication in Science, Technology & Human Values. The researcher is the lead author on the manuscript (see: Appendix A18.2).

generalisable truths as justification for action, although this should not be taken as a positivistic, objectivist pursuit because the truths are imperfect and necessarily located in a historical and social context (Bauman 1978, p.14).

Rational discourse provides criteria for evaluation of interpretations in hermeneutic dialogue, albeit criteria only comprehensible within the TCA. Outcomes of a dialogue can therefore be judged as more or less valid by fulfilment of the ideals of rational discourse. As a procedure for ascertaining truth and deciding between valid interpretations of phenomena, rational discourse cannot be met in practice, serving instead as a critical guide for evaluation of existing discourses (Gilder 1987; Huttunen 2000). The importance of the TCA in terms of empirical research is that it can ground evaluations of the quality of research and dialogue (see: Section 6.1.3.3.1). From a theoretical perspective, it adds an evaluative component missing from hermeneutics.

6.1.3.4 Conclusions

To summarise, hermeneutic understanding is based on a fusion of preconceptions, confounded expectations and new perspectives. As people inevitably bring different preconceptions to situations, it follows that differing interpretations of a situation are inevitable. The existence of differing interpretations is both good and necessary within hermeneutics; in order to develop understanding, individuals must be open to different perspectives that can be incorporated into their interpretation of a situation (Widdershoven 2005, p.65; Widdershoven, Abma, et al. 2009, p.239). Without this openness, the individual will be unaware of meanings or interpretations of a situation that fall outside their forestructure, limiting their understanding. This openness does not imply the uncritical acceptance of new perspectives (Gadamer 2004); rather, as Widdershoven (2005, p.66) explains it, “one does not put oneself directly in the place of the other but is prepared to hear what the other has to say and to acknowledge that it may be necessary to change one’s own views about the matter.” This openness is the defining feature of hermeneutic understanding, which according to Gadamer (2004) requires a dialogue in which both individuals are willing to change their perspectives to improve their understanding of a situation. In such a dialogue the participants are not expected to reach identical conclusions (Widdershoven 2005, p.66), but rather to find common points of view that can inform and improve their understanding of a situation. Once this agreement has been reached in dialogue, a *fusion of horizons* has occurred (Gadamer 2004). In fusion, new understanding is created. It is important to conceive

of understanding in terms of communication, as opposed to control or prediction (Patterson & Williams 2002, p.29): the hermeneutic researcher seeks to communicate a better theoretical or practical understanding of a phenomenon, and eschews control over the phenomenon through rigid causal explanations. In this sense understanding is open-ended communication: it remains open to revision as the phenomenon and its meaning, formulated by practitioners, change over time.

In conceiving of the empirical study as a hermeneutic dialogue, its goal can be understood as the development of understanding of the perspectives of potential practitioners, which may not necessarily be comprehensible within the conceptual framework (see: Chapter 4). The relative credibility of these perspectives can be assessed against the ideals of rational discourse. Understood as an endeavour to provide critical insight rather than rigid explanation of phenomena, the fit between hermeneutics, rational discourse and ethical assessment of PHM within the conceptual framework (see: Chapter 4) is clear. The insight provided by hermeneutic methods can be used to check the explanatory power of the conceptual framework from the perspectives of potential users of PHM, identifying weaknesses or areas requiring refinement or expansion in the process, while not accepting all claims regarding potential futures as equally credible (see: Section 7.3.2.3). The framework is taken to contribute to future dialogue on the ethical implications of PHM, helping stakeholders to understand how PHM may change their relationships with medical practitioners and medicalise their relationships with others (see: Section 3.4.1.3).

6.2 Empirical Study Design

With the ontological and epistemological commitments of hermeneutics explained, along with the ideal of rational discourse and the role of dialogue in reaching understanding, it remains to be seen how hermeneutics prescribes the design of an empirical ethics study. Hermeneutics provides an account of understanding in which “the *context* of the information system [PHM], and the *process* whereby the information system influences and is influenced by the context” was developed (Walsham 1993). The translation of a hermeneutic epistemology and ontology into an empirical study design reflecting these commitments is described in this section.

6.2.1 Qualitative vs. Quantitative

Hermeneutics precludes the possibility of quantitative approaches to understanding the meaning of social phenomena. Hermeneutic understanding requires texts or other objects of

research which provide words which can be interpreted. As only qualitative methods can produce texts for analysis, the choice was straightforward. Still, it is important to recognise the differences between the two approaches, as both were considered in the early stages of the research project.

Quantitative methods are concerned with variables which can be measured “in terms of quantity, amount, intensity or frequency” (Denzin & Lincoln 2000, p.8). These variables are often explained in terms of statistical relationships which presume regularity or predictability, often leading to claims of quantitative research being “value-free” or based on an objective external reality (Denzin & Lincoln 2000, p.9) despite criticisms of the alleged objectivity of numbers and statistical representations (Bauman 1978; Molewijk et al. 2003). The focus on quantifiable data and statistical relationships contributes to a reductionist view of the social world, which precludes discussion of the rich context in which phenomena occur (Casterlé et al. 2011, p.234). As quantitative methods require measurement and the identification of statistical relationships, it is incongruous to imagine their use in uncovering unknown moral beliefs and ethical issues which are complex and embedded in a social and historical context. Even if moral beliefs could be explained in statistical terms, it is unclear how knowing the statistical prevalence of a moral belief could inform the ethical debate in deciding which actions *should* be taken.

This is not to preclude statistical descriptions of normative positions; rather, the prescriptive weight that should be given to statistical representations is unclear. The fact that a moral belief is held by a percentage of positions does not provide a normative reason to accept or enact that belief; a majority of people can hold a morally reprehensible belief. To reason from statistics directly to prescription, an act akin to “might makes right,” is to misrepresent the purpose of ethics as a discipline, conceived of as the pursuit of a good life through moral actions based on a clear conception of right and wrong (see: Section 3.1.1).

While populations may disagree on what constitutes a ‘right’ action, the need for normative claims, moral values, principles and theories to guide these decisions is clear. Ethics would be an incoherent discipline if this were not the case. If all that is needed to determine a morally correct action is a statistical survey of the beliefs of stakeholders, then moral disagreement would not exist; the mere existence of disagreement indicates that reasons beyond statistical prevalence constitute normativity, meaning that statistical representations in themselves do

not hold the key to right and wrong actions, or ethical acceptability. As a result, quantitative methods do not provide a suitable approach (on their own) to identifying, analysing and comparing normative claims made in response to emerging technologies.

In contrast to the weaknesses of quantitative methods in ethics research, qualitative methods emphasise “the qualities of entities and...processes and...meanings that are not experimentally examined or measured ...in terms of quantity, amount, intensity or frequency.” Qualitative methods tend to address social constructions, the relationship between researchers and these constructions, and how this relationship and other “situational constraints” affect inquiry, demonstrating that inquiry and knowledge are both value-laden (Denzin & Lincoln 2000, p.8). This type of context is gathered because, “human behaviour...cannot be understood without reference to the meanings and purposes attached by human actors to their activities” (Lincoln & Guba 1994, p.106). As a result researchers often use qualitative methods within hermeneutic, interpretive, critical and constructivist paradigms to explore how social reality is created and given meaning by social actors (Denzin & Lincoln 2000, pp.8–9). Methods of qualitative inquiry include structured, semi-structured and unstructured interviews, surveys, focus groups, and ethnographies.

Qualitative research is often useful in forming knowledge about phenomena and beliefs about which little is known (van Hooren et al. 2008, p.167), such as the ethical implications of PHM. This usefulness is a product of the ability of qualitative methods to capture meanings participants assign to phenomena (Casterlé et al. 2011, p.234). Meaning is captured through interviews, focus groups, ethnographies and case studies that focus on the context and beliefs of a group of practitioners (Lincoln & Guba 1994, p.106). Qualitative methods therefore contrast the tendency of quantitative research to strip data of secondary variables or context that may ‘corrupt’ results in the pursuit of objective understanding. Given the rejection of objectivist ontologies and the importance of contextual understanding in hermeneutics, a qualitative approach is the most appropriate for the empirical study.

6.2.2 Case Study

A case study is an intensive examination of one or a few selected instances, groups or events of research interest (Stake 1995, pp.435–7), often involving observation of stakeholders and examination of multiple sources of information including texts, memos, interview transcripts and others. Cases can involve any number of actors, networks and events, but will typically

involve “individuals or organisations, simple through complex interventions, relationships, communities, or programs” (Yin 2003).

In principle, case studies are very compatible with hermeneutics and empirical assessment of potential futures. Analysis of changes in attitude over time can be pursued through prolonged interaction with a single case (Searle 1995), for example in studying attitudes pre- and post-deployment. Emphasis is placed on the interaction between researcher and participants because knowledge created in the case study is inevitably shaped by both the participants and the researcher interpreting their actions and opinions (Crabtree & Miller 1999; Baxter & Jack 2008). Context is acknowledged as central to the development of in-depth understanding (Lather 1992; Yin 2003; Baxter & Jack 2008), which provides both insight into current practices as well as a basis for creating and refining theoretical concepts. Longitudinal data collection from multiple sources within the clearly defined parameters and goals of the study allow for in-depth understanding of the complex social relationships that occur within a phenomenon (Feagin et al. 1991, pp.6–7) or practice. By focusing on a small number of data sources a depth of analysis is possible that is not practical in representative studies involving large samples. As dialogue is the main tool of hermeneutics, a research format is required which allows for dialogue across multiple stakeholders sharing a background or frame of reference which shapes their prejudices—case studies achieve this through focusing on an individual practice, phenomenon or context.

With its focus on in-depth, contextual understanding of social phenomena as the basis for theory, the case study method appears appropriate for the refinement of the conceptual framework through empirical assessment of existing relevant practices and practitioners (e.g. disease groups). The study can be conceived of as a case study, albeit with significant qualifications. As an emerging technology, data collection is limited to development reports, academic discourse and collection of attitudes regarding potential uses; user observation is largely precluded beyond pilot studies because the technology is not yet widely used or commercially available.⁵⁹ Stemming from the impossibility of observation, longitudinal data collection is not desirable because potential users will not encounter the technology at any point in the study, meaning their attitudes would not be reflective of (and changed by) practical experiences with the technology (cf. Searle 1995; Latour & Venn 2002), limiting the value of repeated data collection.

⁵⁹ Ethnography was rejected as a design for the study on this basis.

Instead of longitudinal data collection, two instances can occur for each participant to allow for potential changes in attitude over a short period of time, caused by prior unfamiliarity with PHM. As an emerging technology, PHM is likely to be unknown to most potential users prior to the start of the study, meaning a chance to reflect on the implications of the technology would be limited to the duration of a single data collection event. Under the assumption that the formation of rational or well-informed attitudes requires reflection over time, a second instance of data collection appears justified. This period of reflection should increase the quality of the data by expanding the range of issues and quality of arguments seen in dialogue with participants. Based on these qualifications, it is perhaps more accurate to refer to the empirical study as an 'exploratory case study', focused on the refinement and expansion of theoretical understanding of the ethical implications of PHM.

6.2.3 Sampling

Qualitative research typically focuses on a small number of participants to develop an in-depth understanding of the phenomenon under study (Miles & Huberman 1994). In line with this goal, purposeful recruitment according to sample criteria identified by the researcher as relevant to the research topic is typically preferred to a randomised approach (Mays & Pope 1995, pp.109–10; Reed 1996, p.54; Tuckett 2004, pp.2–3). According to Tuckett (2004) qualitative sampling is usually purposive⁶⁰, in the sense that the sampling criteria can be iteratively revised as the study progresses. This approach is coherent with the hermeneutic circle metaphor, in which new evidence and perspectives are constantly sought to expand the horizon of the researcher.

In purposive sampling 'representative types' are used to define a desired sample. Representative types describe the experiences, beliefs or practices that make participants both interesting in the context of the research question, and unique among the sample (Patterson & Williams 2002, p.41). Purposive sampling fits well with hermeneutics, which emphasises the role prejudices play in framing a person's experience of reality, leading to unique interpretations and individualised perspectives of phenomena. On this basis purposive sampling is the preferred method for the study, with recruitment criteria updated as the study progresses.

⁶⁰ Theoretical sampling is also often confused with purposive sampling in methodology literature. Both types of sampling involve selecting specific participants based on criteria determined by the researcher, although theoretical sampling places more emphasis on the development of theory in participant selection. See: Morse 1991; Coyne 1997; Higginbotham 2001.

6.2.4 Data Collection

Many methods of data collection potentially meet the commitments of hermeneutics, including focus groups and interviews. Data collection methods can be judged as more or less suitable to hermeneutics research according to structure, limitation of topics and opportunities to question and criticise claims. Structured methods including questionnaires (self-completion surveys) and structured interviews (Fontana 2000, p.649; Gilbert 2008) are ill-suited to hermeneutics research due to worries that such approaches “impose the researcher’s concepts on the respondent,” prohibiting probing and clarification in the (misguided) pursuit of objectivity (Patterson & Williams 2002, p.25). From the perspective of hermeneutics new understanding is achieved through open-minded dialogue (see: Section 6.1.3.3), meaning the researcher must be willing to explore topics of interest to practitioners. Imagining research as a hermeneutic circle (see: Section 6.1.3.2.2), an iterative approach to data collection was required, in which “insights from earlier interviews are used to guide and improve subsequent interviews” (Patterson & Williams 2002, p.43). Structured methods should therefore be rejected for studies designed as a dialogue because in the former the content of the research tool must remain the same throughout the study to reduce bias (Britten 1995; Fontana 2000, pp.649–51; Patterson & Williams 2002, p.27). Rigid structure is incompatible with open-minded dialogue—static research tools limit the researcher’s ability to probe for further information and explore topics of interest to the participant during dialogue.

For dialogue, semi-structured interviews are preferable because they avoid the limitations that come with preformatted questions and a limited set of topics, while providing enough structure to remain within a general topic (e.g. reactions to PHM).⁶¹ Through the use of an interview guide (Britten 1995, p.1; Gilbert 2008) listing themes and topics of interest, interviews can remain on-topic while the researcher remains free to explore topics of interest to the participant and probe for further contextual information including details regarding the participants social and medical relationships. This freedom to follow tangents and topics the respondent finds important is a mechanism for identifying perspectives unforeseen by the

⁶¹ The terminology in qualitative methodology literature is not uniform. Interviews without pre-formatted questions are alternatively referred to as semi-structured and unstructured (Britten 1995; Fontana 2000; Gilbert 2008). The terminology is not of particular importance here, as long as it is clear that the interviews were conducted with an interview guide which listed topics and findings from earlier in the research cycle. The interviewer was free to raise or ignore these topics, concepts and perspectives as he saw fit, depending on the proceedings of each interview.

researcher of relevance to the conceptual framework, and satisfies the 'open-minded' requirement for hermeneutic dialogue from the researcher's perspective.

Focus groups may also allow for dialogues between multiple participants, but in-depth questioning of claims may be more difficult in a group discussion (Kitzinger 1995). Approaches based on hermeneutics involving the collection of empirical data in bioethics have used focus groups in the past as a way to involve stakeholders with contradictory interests in dialogue (Widdershoven & van der Scheer 2008; Widdershoven, Abma, et al. 2009). This approach has been used to solve moral problems in a specific context in which contradictory claims or moral values must be reconciled, such as the use of coercion in mental health care (Widdershoven & van der Scheer 2008). For an exploratory case study focus groups are inappropriate because a solution to a particular ethical issue is not sought, but rather refinement of the conceptual framework through insights from a variety of stakeholders speaking about potential (as opposed to existing) uses of a technology. Even if focus groups can be used for 'theory-building' in this sense, exploring individual claims in-depth to the same degree as is possible in one-to-one interviews is difficult with multiple participants in a dialogue; extended questioning of individual claims risks alienating other stakeholders or introducing confusion into the dialogue regarding the source or reasoning behind the original claim. Focus groups are therefore an inefficient method to discover *and* understand perspectives not seen in the discourse (see: Chapter 3), or the moral claims, values and specifications of ethical concepts necessary to refine the conceptual framework. Semi-structured interviews are therefore the preferred method for the study.

6.2.5 Conclusions

Based on the ontological and epistemological commitments of hermeneutics an appropriate method to engage patients with unique experiences relevant to PHM is a qualitative exploratory case study consisting of semi-structured interviews with a purposively recruited sample of potential users of PHM. Although an empirical study is necessary to explore the conceptual framework's explanatory power in practice, the researcher's interpretation of the claims of participants cannot be accepted at face value; some criteria for evaluating the credibility or quality of the study's findings are necessary. Appropriate criteria must be sensitive to the decisions made in this chapter; judging a hermeneutic study by positivistic standards, for example, is inappropriate if different paradigms are seen as plausible approaches to research. In this sense evaluative criteria are internal to each paradigm for

research. While validity and rigour have been suggested as criteria for judging the credibility of quantitative and qualitative research in the past (Lincoln & Guba 1994; Mays & Pope 1995; Finlay 2006), neither correctly captures the ideals of rational discourse or the characteristics of hermeneutic understanding, suggesting that appropriate criteria must be built on a hermeneutic epistemology.

6.3 Ensuring Research Credibility in Hermeneutic Research

Widely accepted criteria to evaluate the quality of interpretivist and hermeneutic qualitative research, similar to those found in positivistic evaluations of validity or rigour (e.g. Popper 1959), do not exist despite repeated attempts in recent decades to come to a consensus (Mays & Pope 1995; Finlay 2006). That the study assesses an emerging technology, which by definition creates uncertainty, means that a clear approach to evaluating quality is especially relevant.

6.3.1 Truth, Validity and Credibility

It has been claimed that the TCA (see: Section 6.1.3.3.1) can bring social research (and ethics) as close as possible to the standards of truth in the natural sciences (Bauman 1978, p.243), measured in terms of validity. Whether or not this is true, it is not clear that 'validity' is an appropriate standard to judge the quality of hermeneutic research, despite its position in the TCA and rational discourse (see: Section 6.1.3.3.1). The reason for this can be seen in the difference between *absolute truth*, or a correct description of external reality, and *moral truth*, or a justified reason to act. The difference is expressed in the distinction between validity and credibility, understood as measures of truth claims in objectivist and constructivist ontologies, respectively. Truth claims are essentially claims to knowledge, which was defined by Plato as "justified true belief," or belief which is accompanied by justification in the form of reasons and rational argumentation (Plato 1987; Bostock 1991). In a 'situated' conception of reality as existing between external structure and socially created realities (see: Section 6.1.3.1), validity and credibility can both ground truth claims:

Validity – Defined here along critical rationalist lines in terms of falsifiability (Popper 2002).

Something is valid only so far as it is falsifiable. Claims to knowledge, or scientific theories, are increasingly valid as evidence accumulates in their favour, but they can always be proven false in the future (Popper 1959). It is therefore never true—all human knowledge is irreducibly hypothetical because inductive reasoning cannot logically produce certainty, or truth, without

assuming the truth of the premise to be proven true (Hume 1978). Certainty requires an infinite number of observations which can never be realised in practice. Falsification is therefore preferred as a basis for validity because it recognises the provisional nature of all human knowledge, including scientific laws and theories, all of which can be proven false through a single counterexample. Falsification can occur through empirical observation, which is impossible for future events. Claims about the future cannot, then, be falsified and cannot therefore be valid. With this said, claims may take valid (empirical) observations about existing phenomena and make judgments about the future on their behalf. In this case the claims cannot be directly valid, as they describe the future, but their existing empirical basis may be valid. Such future claims may, however, be simultaneously invalid and credible.

Credibility – Credibility is a summarising judgment of the normative truth content of a claim, judged according to standards of truth accepted between and within individuals. Credibility is not a binary judgment; claims are more or less credible according to how closely they adhere to the accepted standards of truth. This is not to say that credibility brings us closer to *absolute truth* or certainty; to say something is credible is to say that we have reasons to act as if it is true. Credibility thus brings us closer to *moral truth*, meaning it provides justification for action. Norms of conduct can be derived or based upon credible claims (Bauman 1978, p.241). Depending upon one's standards, validity, understood as a measurement of falsification, will also contribute to the credibility of a statement. Many possible standards of credibility exist: persuasiveness, insightfulness, practical utility or trustworthiness, transparency, reflexivity and coherence (see: Section 6.3.2). It is argued that all of these standards come into play in judging the credibility of the research project at multiple levels. Persuasiveness, insightfulness, practical utility or trustworthiness, transparency and reflexivity are standards to judge the success of the researcher in providing a credible account of the moral beliefs of practitioners through empirical research.

Positivist measurements of validity in terms of bias, falsifiability and reproducibility (e.g. Popper 1959) should be rejected in hermeneutic research as contradictory to hermeneutic epistemology—interpretation and understanding are subjective and vary from person-to-person and context-to-context, built as they are from prior knowledge and prejudices unique to individuals.⁶² Credibility is an expression of the force with which a belief is held; Habermas'

⁶² Attempts have been made to adapt positivist validity criteria to qualitative research by evaluating quality of in terms of 'rigour'. Such attempts have so far failed to establish criteria built around

validity claims (see: Section 6.1.3.3.1), despite their name, can be understood as an evaluation of credibility, not validity, in the terms described here because the purpose of discourse is justified action or moral truth. Labelling a claim as credible identifies it as convincing or worthy of belief, or “that it is believed by an agent who is free not to believe it, that is, by an observer who, after exercising judgment and (possibly) intuition, chooses to accept the proposition as worthy of his believing it” (Weizenbaum 1976, p.16). Criteria for establishing credibility must then focus on the act of interpretation as carried out by the individual. Credibility suggests that contextual understanding of the interpretations of participants should be sought through dialogue, resembling rational discourse as far as possible. Dialogue requires close interaction between researcher and participant, so researcher influence or ‘bias’ should not be seen as a problem in hermeneutics research, although a reflexive account of how dialogue occurred and the researcher’s influence on the participant should be provided.

Hermeneutics research pursues open-ended understanding as an ‘end product’, recognising that social interactions do not occur in a closed system with causal relations (Patterson & Williams 2002, p.28) amenable to prediction and reproduction of findings. This is not to say hermeneutics research cannot produce theory or conclusions relevant to other similar contexts, but rather that a significant degree of uncertainty is necessary when generalising. Validity criteria are seen as reproducing “only a certain kind of science,” one that “silences too many voices” (Denzin & Lincoln 2000, p.10) in the pursuit of objectivity. For research into social reality and interactions endorsing a constructivist or co-constituted ontology (see: Section 6.1.1.1) a static external reality against which validity can be defined in terms of falsifiability and reproducibility does not exist (Finlay 2006). The co-constituted hermeneutics ontology necessitates rejection of validity criteria based on objectivist ontologies. Alternative criteria for hermeneutic research are necessary which focus on the quality of the researcher’s interpretation of a phenomenon or social reality rather than predictive power, falsifiability or reproducibility.

6.3.2 Criteria for Credibility in Hermeneutics Research⁶³

A central distinction for determining appropriate credibility criteria for hermeneutics research exists in the difference between methodological and outcome credibility. Natural sciences and ‘foundationalist’ researchers tend to emphasise methodological purity as a route to objectivity

interpretivist and hermeneutic epistemologies. For a summary of prior approaches to rigour and their relation to validity, see Appendix 7.

⁶³ These criteria are meant to be applied to the findings presented in Chapter 9.

or 'certainty in knowledge' (Patterson & Williams 2002, p.35). Hermeneutics asserts the impossibility of objectivity and truth through methodological rigour because human understanding is necessarily rooted to a particular perspective. As a result, distance cannot be created between the self and personal perspectives or bias (Polkinghorne 1983, p.224). To do so would be to transcend the limitations of human experience.

Realising these limitations, credibility must be established in part through evaluation of the outcomes of research. The following outcome-oriented criteria are proposed to evaluate the credibility of the empirical study:

- **Persuasiveness** refers to the degree to which the reader of the research report can take the viewpoint of the researcher, and understand the reasoning behind his interpretations. While the reader cannot empathetically completely take the researcher's perspective, he should be provided with enough examples from the data to justify the researcher's interpretation (Patterson & Williams 2002, p.33). Persuasiveness is therefore a judgment of the quality of the dialogue between reader and text, which depends on the quality of the researcher's report of the results. Research which is successfully persuasive will contain enough detail for the reader to have a clear picture of the researcher's role in the project, and influence over its findings (Butler 1998; Maxwell 1998, p.243). Persuasiveness directs concerns over credibility away from predetermined levels of agreement between multiple independent analyses, and focuses instead on the conclusions reached in the research and the strength of arguments and evidence supporting those conclusions (Patterson & Williams 2002, p.33). An evaluation of the reasoning and justification supporting the researcher's interpretation of the data is central to the concept.
- **Insightfulness** refers to the quality of the researcher's interpretation, judged in terms of its ability to go beyond merely summarising the phenomenon by revealing a new insight or theoretical strand which presents the phenomenon in a new light (Patterson & Williams 2002, pp.34–5). The researcher's interpretation should therefore provide a unique theoretical perspective seen as convincing by the reader. Insight involves connecting, interpreting and arranging data in a way that reveals new meanings or aspects of the phenomenon under study (Polkinghorne 1983, pp.238–9). A qualitative study is considered insightful if the researcher's interpretation increases the reader's understanding of the phenomenon (Patterson & Williams 2002, pp.33–34).

Insightfulness is similar to prior accounts of 'rigour' as an evaluative mechanism for qualitative research (see: Appendix 7), intended to ensure "a plausible and coherent explanation of the phenomenon" (Mays & Pope 1995) is produced. To be both persuasive and insightful, the reader must be interpretively "guided through the data in a way that produces an understanding of the phenomenon reflecting greater insight than was held prior to reading the research" (Patterson & Williams 2002, p.34). Thus, the researcher provides new, interesting insights into the phenomenon, while providing enough of an 'audit trail' to allow the reader to reach subjective assessments of the researcher's conclusions.

- **Practical utility** is a functional criterion, by which the research is judged for its contribution of knowledge or an answer to the research question(s). It has been related to 'trustworthiness', which refers to the soundness of the methods and interpretation of the researcher as judged by others familiar with the 'tools' and methods of research (Patterson & Williams 2002, p.35). The research must therefore contribute to the discourse on the object of study to be deemed credible. Recall that understanding is an end product of hermeneutics, meaning 'addressing' a problem does not necessarily involve a solution, but rather insights or understanding into the phenomenon. To be considered useful, research must be 'trustworthy' by reviewing prior work in the field before designating a research question and interpreting the data. Therefore, it would seem practically useful research must involve theoretical insights, such as those offered above (see: Chapter 4).

The above criteria help evaluate the quality of the outcomes of empirical research within hermeneutics. Complementary methodological criteria are necessary to define credible reporting of research conduct and results, allowing the reader to follow the experiences and reasoning process of the researcher in interpreting the data. The following methodology-oriented criteria are proposed:

- **Transparency** refers to the level of detail provided about the method of the research, and the researcher's reasoning process in reaching conclusions. It can also be referred to as researcher 'honesty'. Although qualitative research is often described as a messy process, it should be clear how, when and by whom it was performed (Kuper et al. 2008, p.688). This is especially true of data analysis in which the source of perspectives and interpretations becomes paramount. An "audit trail" is required

which allows the reader to understand how the research methodology was actually applied in the study (Guba & Lincoln 1985; Finlay 2006, pp.8–9). The researcher must provide a detailed account of the hermeneutic dialogue and process of interpretation to explain how his understanding of the topic developed. Sufficient detail and ‘raw data’ are necessary to allow the reader to follow the researcher’s reasoning process.

- **Reflexivity** is the usage of critical self-reflection in the evaluation of a phenomenon (Holloway 2005; Finlay 2006; Stahl 2008). In the case of qualitative research, the phenomena are the method and outcomes of the research. Reflexivity is connected to transparency, in the sense that the former increases the latter. A reflexive approach should be taken in reporting the proceedings of the study, by which the researcher critically evaluates the relative successes and failures encountered along the way (Guba & Lincoln 1985; Ives & Dunn 2010, p.261). Reflexivity is an important ideal in writing up research findings to ensure the process of dialogue, interpretation and fusion of horizons are clearly transmitted to the reader, thereby contributing to persuasiveness and practical utility. At a minimum, the researcher needs to provide a description of his prejudices at the beginning of the research study, and document how it changed through encountering alternative perspectives in dialogue.⁶⁴ A critical perspective is necessary for self-evaluation, so the researcher should detail which perspectives were the most influential and those which he rejected. Initial assumptions, beliefs and ideologies should be openly questioned (Stahl 2008), and apparent in writing up results. A reflexive, transparent account of the research process ensures understanding did not stagnate at some point in the study, which should not occur if the research process is meant to be an ongoing hermeneutic circle.

Reflexivity also refers to the consideration of alternative interpretations and perspectives in data analysis. In a qualitative study it is unlikely that all the data will fit the researcher’s interpretation at the end of the study. While it is tempting to ignore discrepant data undermining the researcher’s interpretation, both discrepancies and alternative interpretations of the data must be considered for a study to be reflexive (Maxwell 1998, p.245; Finlay 2006, p.10). Evidence of this consideration is necessary; reasons for rejecting alternative interpretations and dismissing discrepancies may be enough. Alternatively, the discrepancies can be presented to allow the reader to judge

⁶⁴ Such an account can be seen in Chapters 1 through 4.

for themselves whether the researcher's interpretation is credible (Maxwell 1998, pp.244–245). In the empirical study alternative interpretations were considered in dialogue, especially in specifying ambiguous ethical concepts such as privacy. In a sense, reflexivity ensures that the conclusions reached on the researcher's interpretation of the data are logical, by exposing the reasoning process to the reader's scrutiny. Logic, a cornerstone of philosophical justification (Ives & Dunn 2010, p.258), still exists within the concept of credibility, although it is focused on the quality of the individual hermeneutic interpreter, not a disembodied ideal of rationality; whether this is sufficient to justify the generalisation of the outcomes of the research across other contexts remains to be seen.

The concept of reflexivity can be bolstered through connection with Habermas' procedural approach to discourse described in the TCA (Habermas 1984; Habermas 1985) (see: Section 6.1.3.3.1). As a procedure for arriving at moral truth, rational discourse reminds us that credibility criteria cannot be entirely outcome-oriented. By judging the outcomes of the empirical study according to the above criteria, the *initial credibility* of the empirical data can be demonstrated, assuming the study at least partially fulfilled the Habermas' ideals for communicative action (cf. Habermas 1992). The ideals of rational discourse therefore clarify the epistemic status of the outcomes of the empirical study. To do so, they must be used to evaluate the method and outcomes of data collection. The interviews and data analysis can be judged by these ideals to determine the credibility of the outcomes, according to how close the interviews came to Habermas' ideals. While the ideals are impossible to realise in practice, the researcher's openness to alternative perspectives and the success of the best argument, regardless of its origin, can be evaluated in reporting the findings of the study. This connection between the TCA and the epistemic status of claims encountered in the empirical study is expanded further below (see: Chapter 7) in relation to the difficulties of evaluating uncertain futures.

6.3.2.1 Credibility and Review

To ensure the researcher's report is sufficiently persuasive, insightful, useful, transparent and reflexive, a review process should be implemented into qualitative empirical research based on hermeneutics. Interpretations can be checked and alternative perspectives offered by a group of researchers, even if only an initial segment of the data is reviewed (cf. Mays & Pope 1995). Review can be seen as a continuation of the dialogue between researcher and texts

involving other members of the research team to consider new perspectives and potentially, although not necessarily, reach consensus on 'correct' interpretations of the data. While the primary researcher's perspective benefits from having participated in the original dialogue(s), it is still worthwhile to engage in dialogue with other researchers to consider alternative perspectives, theories and explanations of the participants' claims. The goal of review is therefore not validation through agreement upon correct interpretations, although this may occur, but to provide alternative perspectives to be considered in interpreting the data.⁶⁵

6.3.3 Generalisability in Qualitative Research

Criticisms of a lack of generalisability in qualitative research are common (Mays & Pope 1995; Morse 1999). Quantitative research is seen as a legitimate form of "hard science," which reveals causal explanations of phenomena amenable to reproducibility and the evaluative standards of positivism. In contrast, qualitative research "elicits the responses of a participant or researcher at a specific time and place in a specific interpersonal context," precluding reproducibility and generalisation of findings from a single context to other dissimilar contexts (Finlay 2006, pp.4–5). As a result, qualitative research can be incorrectly viewed as less valuable or rigorous than positivistic research.

By exploring the perspectives of stakeholders and researchers in-depth, with intimate knowledge of context and social relationships, qualitative research can provide detailed understanding of a phenomenon through focusing on individual responses and specific occurrences, rather than broad populations (Patterson & Williams 2002, p.25). It is therefore inappropriate to criticise qualitative research for a lack of acontextual generalisability because it is precisely what is not being sought (cf. Denzin & Lincoln 2000, p.10); qualitative research seeks to develop contextual, individualistic understanding, as opposed to group-level generalisations. This aim does not mean that qualitative research lacks generalisability, but rather that generalisation must be separated from statistical significance. The possibility of qualitative generalisation requires a better understanding of the types of generalisations that can be made across diverse contexts of study in which similar phenomena occur.

6.3.3.1 Types of Generalisations

The possibility for qualitative generalisation has been described as 'transferability' or 'resonance' (Guba & Lincoln 1985; Marshall & Rossman 1999, p.193; Williams 2000; Finlay

⁶⁵ The review processed carried out in the research reported here is described in Section 8.5.2.

2006, p.10; Kuper et al. 2008, p.688), which refers to the applicability of findings from a study to similar contexts or phenomena. In transferring findings such as theoretical insights to new contexts, consideration of the uniqueness of the new context compared to the original context of study is required before transfer is justified.

In practice, transferability is assisted by reference to “the original theoretical framework” of the study whose findings are being transferred, in which it can be shown “how data collection and analysis [was] guided by concepts and models.” Researchers can then compare phenomena and contexts falling within “the same parameters” to the original project, identifying theoretical and methodological similarities which justify transfer of conclusions from context to context (Marshall & Rossman 1999, p.193). Qualitative generalisations therefore require the identification of common characteristics between contexts. But what exactly is being transferred? A classification of three forms of generalisation by Williams (2000, p.215) suggests types of statements or findings from hermeneutics research that can be transferred to other contexts:

1. **Total Generalisations** – Axioms, by which a situation is shown to be an example of a “general deterministic law.” Total Generalisations are therefore not generalisations as such, but instances of a scientific law. Williams gives the example of “the rate of cooling of an electric element is an instance of...the second law of thermodynamics.”
2. **Statistical Generalisations** – Probabilities and predictions, “where the probability of situation *S* occurring more widely can be estimated from instances of *s*. Resting on a probabilistic “relationship between sample and population,” Statistical Generalisations are the type most commonly made in the physical and social sciences, in instances in which relevant scientific or mathematical laws do not exist. A researcher is thus able to “express statistically the level of confidence she has that her sample represents the population.”
3. **Moderatum Generalisations** – Interpretive or theoretical generalisations, in which “aspects of *S* can be seen to be instances of a broader recognisable set of features.” Researchers identify important interpretations, perspectives or features of a context or phenomenon which can then be transferred to other

similar contexts or phenomena, but not without supporting arguments and evidence that demonstrate shared characteristics (Williams 2000, p.215).⁶⁶

To apply this classification to the empirical study, technologies must be understood as embedded in social reality, rather than existing externally to it. While technological artefacts exist beyond the social world in physical form, their meaning and importance is created through social interactions (cf. Latour & Venn 2002). The process of meaning-making goes both ways—while humans attach meaning to technologies, interactions with the technology change the expectations and prejudices of humans. *Moderatum* Generalisations are possible in qualitative hermeneutic research based on a co-constituted ontology, meaning reality is not entirely relative or purely socially constructed.

Grounding *Moderatum* Generalisations are different types of “categories” which vary in transience and ontological status across contexts (Williams 2000, p.218). Of these categories, those related to physical or technological characteristics are seen as the less transient, initially forming a more reliable basis for generalisations than interpersonal and cultural categories. As an example, GPS devices share common technological characteristics regardless of the context of use, but the meaning and uses attached to the device will vary according to social, cultural and individual characteristics and goals. However, generalisations of the type, “Most GPS devices include mapping functions,” are of themselves uninteresting in sociological and normative terms. *Moderatum* Generalisations proceed beyond such simple statements about the likelihood of shared functional characteristics in generalising about social phenomena and contexts. The legitimacy of *Moderatum* Generalisations can be grounded in “cultural consistency” (Williams 2000, p.220) which frames the variety and transformation of social phenomena and contexts. Cultural consistency describes the shared terms, meanings, experiences or “social order” which makes social life possible, by creating a shared foundation upon which an individual’s forestructure of understanding is built. Cultural consistency and

⁶⁶ The debate over generalisations in qualitative research need not be viewed as a dichotomy according to this classification: proponents and critics are both correct, although about different types of generalisations. Total and Statistical Generalisations are not made in qualitative research because qualitative data does not allow for quantitative measurement or calculation of probabilities. If critics of qualitative generalisation (e.g. (Guba & Lincoln 1985; Mays & Pope 1995; Morse 1999) are referring to these types of generalisations in denying their possibility in interpretive research, then they are correct. On the other hand, *Moderatum* Generalisations can be made in qualitative research, and are seen as an appropriate research goal (Maxwell 1998, p.246; Morse 1999; Williams 2000, p.215; Patterson & Williams 2002).

technological characteristics can thus be viewed as part of the 'structure' spoken of in co-constitution (see: Section 6.1.3.1).

6.3.3.2 *Moderatum Generalisations in Ethical Assessment of Emerging Technologies*

Moderatum Generalisations can be made about the future ethical implications of PHM (when it is seen as embedded in the social world) by identifying important features about its technological characteristics, contexts of use, and intended outcomes. In preparing social responses to these features, ethics moves from a reactive to proactive practice, and may prevent ethical harm in the process. Concerning ethical decision-making, cultural consistency is not the same as 'common morality' (cf. Beauchamp & Childress 2009); within a culture, individuals are free to have unique, equally legitimate experiences and interpretations, and to assign different value and specifications to normative concepts and issues. For example, while individuals may share a concern for privacy, the content and relative value of the concept will vary. Still, across the specifications of privacy a shared foundation must exist (or be assumed to exist) for individuals to understand each other in social interactions.

It would appear that making legitimate generalisations, transferrable to other contexts with supporting arguments, in hermeneutic research assessing ethical implications of an emerging technology requires understanding the interpretations and experiences of participants, as well as the normative cultural consistency which makes possible social interactions. While statistical probability is not attached to the generalisations, they provide a set of characteristics to which future instances of the phenomenon and context under study can be compared. If similarities are found, conclusions matching or derived from the shared characteristics can be transferred and re-assessed in the new context. As with Statistical Generalisations, *Moderatum* Generalisations do not say that the generalisations are absolutely true or will occur with any certainty; rather, they provide empirically grounded reasons for interpreting instances of a phenomenon in the theoretical framework established by the original study. In this case, the generalisations made regard the identification and interpretation of ethical implications in potential future uses of PHM.

6.3.4 *Generalisations and Credibility*

This account of qualitative generalisation speaks to the implications of combining theoretical and empirical data in the construction of a conceptual framework for PHM. The qualified generalisability of claims made in the empirical study ensures that refinement of the

conceptual framework on the basis of empirical findings is justified, and does not limit the applicability of the framework only to the participants or context studied here. Assuming the methodology and outcomes of the study are judged credible, the combination of empirical and theoretical data for the construction of an ethical conceptual framework for PHM is methodologically sound.

6.4 Conclusion

The choice to engage in hermeneutic dialogue with potential users of PHM is intended to explore the ethical implications of PHM for medical and personal relationships. Hermeneutics enables the researcher to critically assess the unique perspectives and prior knowledge of individuals resulting from their experiences with practices relevant to PHM, such as chronic illness management or caring for a dependent family member or friend. The assumption of this approach is that the experience of having (or caring for someone with) a chronic medical condition informs the moral beliefs of practitioners when considering adoption of emerging medical technologies in the future—in this sense the ‘experience of disease’ or ‘experience of caring’ are the practices in which practitioners are engaged. This assumption is justified according to hermeneutics, with its implications for the credibility of participant claims in ethical discourse explored below (see: Section 7.2.1). By engaging with the researcher in dialogue and reflecting on future use of PHM in their lives, these practitioners provide perspectives against which the conceptual framework may be applied and refined. Besides assisting in ‘theory building’ in this regard, the outcomes of the empirical study can be seen as qualified generalisations transferable to similar contexts and phenomena.

The empirical methodology detailed in this chapter can be seen as responding to some of the requirements posed in research question 4 (see: Section 5.6). At this point the methodology demonstrates how the moral beliefs of potential users of PHM can be captured through dialogue; however, the methodology does not yet explain how these beliefs can be considered in ethical analysis, or how the uncertainty of the future affects the credibility of the empirical data.

To address these requirements, it is necessary to consider the methodology within a recent movement in ethics advocating the combination of ethical theory and empirical research in ethical analysis. For empirical research into potential futures, this combination raises important questions related to the epistemic status of normative claims made under

conditions of uncertainty, and the importance they should play in understanding and responding to predicted ethical implications. For uncertain claims gathered and assessed through empirical research to be used as a 'test' of the conceptual framework's explanatory power and limitations, and to refine the framework against them, the epistemic status of uncertain claims relative to claims about existing practices must be clarified prior to application of the framework. Failing to explain the relative epistemic status of uncertain normative claims to this extent would mean that the application of empirical data to the conceptual framework could not justify the framework as a credible way to explain, or 'make sense' of, the various ethical implications of PHM (see: Chapter 3). Such an account, which expands the methodology developed here to respond fully to the requirements of research question 4, is detailed in the next chapter.

7 Chapter 7: The Problem of Uncertainty in Ethics of Emerging Technologies

7.1 Introduction

Ethical assessment can be seen as the basis of moral decision-making when attempting to find a solution or 'right' action for a particular case (see: Section 3.1.1). However, ethical assessment also provides a basis for the development of theoretical understanding of a phenomenon, such as an emerging technology. It is this latter aspect of ethical assessment which is pursued in this project. To justify the refinement of the framework on the basis of empirical data uncertain normative claims encountered in the study need only be shown to be initially credible, or morally justified to some degree, to be used for this purpose. Particular claims need not be endorsed as 'correct' in terms of moral decision-making because a particular case does not require resolution. In other words, it must be shown that moral beliefs about potential futures possess some sort of value to be taken seriously in ethical discourse, thereby justifying the empirical study's role in exploring and refining the conceptual framework. The necessity of resolving this problem is not limited to the current study; any attempt to ethically assess emerging technologies, or to prescribe proactive actions intended to address potential ethical problems based on predictions about the future, implicitly requires that uncertain normative claims be seen as at least initially credible or plausible justification for action.

The initial credibility of uncertain normative claims meeting certain conditions in ethical discourse is defended below. The defence requires two distinct components; one relating to the plausibility of connecting theoretical and empirical approaches to ethical assessment requires exploration, and the other to the epistemic problems caused by uncertainty. Without credible arguments for each the attempt to build and refine a conceptual framework based on a combination of theoretical insights and (un)certain empirical data cannot be epistemologically and methodologically justified.

7.2 The Integration of Empirical Data and Theory in Ethical Analysis

In recent years the combination of theoretical and empirical insights in ethical analysis has been advocated in applied ethics. This movement, called 'empirical ethics', needs to be understood as a *mindset* towards ethics, not a *method* for doing ethics. As a recent

development in the field of applied ethics it does not yet possess a standard methodology (Ives & Draper 2009; Hurst 2010; Dunn et al. 2012), although methodological unity is not necessary to argue for the inherent compatibility of theoretical and empirical approaches to ethical analysis.

Historically, empirical data has had a supportive yet detached relationship with ethics. Social scientists and ethicists have often worked separately on a project, with the former responsible for gathering empirical data and the latter responsible for analysis and drawing normative conclusions (Molewijk et al. 2003, p.71). This division of work stems from the fact-value gap (Hare 1952; Hume 1978), according to which the descriptive world remains the domain of scientists, while the normative world is the domain of ethicists (Molewijk et al. 2003, p.71). Under such a separation ethicists have been limited to using descriptive empirical data to (1) apply ethical theory in the context of a policy or action (Molewijk et al. 2003, p.71; McMillan 2008, pp.17–18), or (2) to assess the validity of empirical assumptions upon which moral theories are based (Leget et al. 2009; De Vries & Gordijn 2009, p.195), or (3) to gain insight into social practices for the identification of relevant cases and stakeholders in ethical deliberation (van Hooren et al. 2008, p.168). Each of these examples upholds the epistemological distinction between description and prescription. Facts and values still therefore fulfil very distinct and separate roles in the research; in these examples, researchers do not collect empirical data to identify or refine moral norms. In this sense the theory is not changed through the process of empirical research, but rather made relevant to a specific context. In these examples empirical data does not tell us how to understand and apply ethical theory in a context, but rather identifies when, where and to whom it can be applied.

In contrast to the above examples, in recent years these methods of research have been challenged through the combination of empirical (typically social scientific) research with ethical analysis (Musschenga 2005, p.468; Hoffmaster & Hooker 2009; De Vries & Gordijn 2009, p.193; Dunn et al. 2012). This movement, called ‘empirical ethics’, has arisen from the recognition that empirical data can be usefully employed in ethical analysis to build and translate ethical theory into “middle-range principles”, refine ethically questionable practices and reach contextually-sensitive normative conclusions for practical purposes including policy guidance (Birnbacher 1999, p.321; Musschenga 2005, p.469; Hoffmaster & Hooker 2009; Leget et al. 2009). Dialogue with individuals involved in a practice can lead to a need to refine the theory, as the application of theory to practical issues reveals its strengths and limitations

(Widdershoven 2005, p.72). Alternatively, theory can reveal how mid-level principles are “differentiated, modified or contradicted by the lived experience of the persons concerned” (Casterlé et al. 2011, p.240), and translated into practice-internal norms of good conduct (see: Section 4.3.1.1).⁶⁷ Such approaches ensures ethical theory, principles and norms are specified, or given meaning, within individual contexts and practices, while remaining open to revision or specification based on practice-internal experiences.⁶⁸

This ‘empirical turn’ in applied ethics is perhaps unsurprising when considering the prevalence of philosophical paradigms and ethical theories which implicitly support the integration of empirical data (e.g. information derived from moral wisdom or practice) in ethics. Gadamer’s hermeneutics (see: Section 6.1.3) and its derivations assert the importance of ethics starting from the moral experiences of individuals confronting existing moral problems (Gadamer 2004; Musschenga 2005, p.485; Widdershoven & van der Scheer 2008), which is related to the virtue of *phronesis* as a source of legitimate normative claims (Widdershoven & van der Scheer 2008; van Thiel & van Delden 2010) (see: Section 4.3.1). Integration is intended to ensure ethics is informed in some way by the social world as experienced by practitioners, whether to ensure that problems of practical importance are addressed or to treat practice as a source of morality (cf. MacIntyre 2007; Leget et al. 2009).

Empirical ethics is best understood as a mindset guiding the use of empirical data in ethical analysis. Proponents are far from unified in terms of philosophical background and methodology, yet they tend to share three basic assumptions: (1) studying the moral beliefs of individuals in a practice yields meaningful information that should be a starting point for ethics (Borry et al. 2004, pp.39–40; Baldwin 2008, p.109; De Vries & Gordijn 2009, p.193; Dunn et al. 2012, p.471); (2) descriptive and normative approaches are inherently complementary; and (3) empirical ethics cannot rely on context alone for its determination of morality, but must

⁶⁷ Mid-level principles refers to principles such as those found in Beauchamp and Childress (Beauchamp & Childress 2009), in which four principles concerning respect for autonomy, beneficence, justice and nonmaleficence are balanced to reach ethical decisions. They are defined in contrast to top-level principles in which one proceeds from a single theoretical premise (such as the utilitarian focus on pain vs. pleasure) to a conclusion.

⁶⁸ For example, ethical principles may require specification when principles and practice-internal norms of good conduct, conflict. Specification requires qualifying or otherwise reducing the scope of application or prescription of the principle to solve the conflict. Rather than adding exceptions or reducing the content of the rule, the specification should reveal how the principle applies in a specific case. The specification is thus “the same as the initial principle,” only with “clauses about the scope of the norm or the nature of the act or end enjoined or proscribed” added to it (Richardson 1990, p.292; Verweij 1998, p.36).

incorporate both empirical data and normative theory to avoid moral relativism (Borry et al. 2004, pp.39–40; De Vries & Gordijn 2009, p.193; Dunn et al. 2012, p.469). The incorporation of empirical data, normative theory and contextual information in ethical analysis defines the empirical ethics mindset (De Vries & van Leeuwen 2010; Dunn et al. 2012).

The majority of approaches to empirical ethics have been designed to solve practical moral problems or provide insight into a particular instance of a phenomenon, for example through dialogue with practitioners and stakeholders (e.g. Molewijk et al. 2004; Goldenberg 2005; Widdershoven & van der Scheer 2008; Ives & Draper 2009; Kon 2009; Leget et al. 2009; Widdershoven, Abma, et al. 2009; Hurst 2010; van Thiel & van Delden 2010). These approaches focus on stakeholders coming to understand and consider each other's perspectives in reaching pragmatic solutions. PHM is not yet this kind of practice—it is not yet a diffuse technology with well understood ethical consequences (see: Section 3.3.6). The goal of the research project is to fill this gap by viewing PHM as an emerging practice around which a conceptual ethical framework can be built to assist in future context-specific ethical analysis. Thus, the project does not seek to 'fix' an existing moral practice, but to develop insight into a future moral practice before problems occur. The creation and application of a conceptual framework built from ethical theory and a discourse involving empirical research (see: Chapter 3) can, however, be considered a form of empirical ethics when supported by empirical research to apply and refine the framework. In this sense empirical ethics can both apply theory to a particular practice, or gain insights from a practice to build or refine theory.

7.2.1 Moral Wisdom, Practices and Practitioners

Using empirical research to generate legitimate normative claims implies that empirical ethicists attribute value to the moral beliefs of individuals involved in practices (or "moral practitioners"), because the practice provides them with unique "moral experiences" (Musschenga 2005; Abma et al. 2010, p.244). If justificatory power for moral decision-making can be attached to the experiences of individuals with particular 'moral experiences' in the form of 'moral wisdom', then the refinement of the conceptual framework based on their perspectives has *initial credibility*.

Moral wisdom is a product of 'moral experiences' from the lives of individuals involved in a practice (Widdershoven, Abma, et al. 2009; Abma et al. 2010). During such experiences decisions are made and justified between 'right' and 'wrong' actions. Moral experiences are

those which contribute to a person's understanding of right and wrong, or the good life, or the internal norms which govern the morality of a practice. Moral experiences are practice-specific; however, experiences occurring outside specific practices affect the development of the moral beliefs of practitioners towards those practices. Moral experiences are "formative," in the sense that moral wisdom develops over time as moral experiences occur, implying that participation in a moral practice will directly contribute to the development (or perhaps more accurately, refinement) of a person's moral compass (DePaul 1993, pp.145–6).

Normative claims are, therefore, a product not only of rationality and reason, but of moral experiences, wisdom, and other aspects of human experience which constrain interpretation. To understand this statement, it is necessary to recall that interpretation is filtered through prejudices. Moral experiences, which require interpretation of an unfamiliar or imperfectly understood situation, are therefore framed by the prejudices of the practitioner, and contribute to understanding a phenomenon or the ends of a practice (e.g. Section 4.3.2). Normative claims influenced by moral experiences are likewise framed, becoming part of the practitioner's prejudices which frame future moral judgment. According to this, moral experiences play an important epistemic role in justifying specific normative claims (Audi 1998, p.363), as they form the "basis of knowledge or justified belief regarding one's moral obligations" (De Vries & van Leeuwen 2010, p.493), thereby giving the normative claims of practitioners about the practice(s) in which they are involved, or through which moral wisdom has been gained, *initial* credibility.⁶⁹

As the source of initial credibility of normative claims, moral wisdom is related to *phronesis*, or practical wisdom gained from lived experiences and social interaction which teaches individuals to identify the morally relevant aspects of a situation (Widdershoven & van der Scheer 2008, p.31). Wisdom enables individuals to choose between different courses of action, identifying the course of action which most closely resembles an ethical ideal or the 'good life' (Abma et al. 2010). Moral wisdom is derived from and unique to practices, meaning

⁶⁹ An epistemological defence of moral experiences and moral wisdom providing initial credibility in moral justification to the normative claims of moral practitioners is offered in Appendix 9. The explanation of the initial credibility of such claims offered here may be vulnerable to criticisms of 'intuitionist' approaches to moral justification. With that said, the approach used here is not intuitionist because normative claims are only granted initial credibility for the purposes of building the conceptual framework and testing its explanatory power. To be used in deciding the correct course of action in a particular case, such claims would require questioning in ethical discourse to be used for moral justification.

individuals involved in practice X will have moral experience Y which is unique to practice X and cannot be experienced outside of it. As a result, practitioners have unique moral beliefs informed by their practice which they can contribute in dialogue—their moral experiences have taught them to discern the morally relevant aspects of their practice (Widdershoven, Molewijk, et al. 2009, p.99). It follows that ethical analysis can treat the moral beliefs of practitioners as an initially credible source of moral justification, assuming the beliefs are based on practical moral experience. This is not to say that the actions recommended by practitioners are inherently justified, but rather that their experiences provide a reason to initially take their claims seriously regarding the moral acceptability of a practice or choice of action.

This attribution of credibility to the statements of practitioners is coherent with (but not limited to) hermeneutics (Widdershoven & van der Scheer 2008; Mingers & Walsham 2010) because practitioners possess unique shared experiences or consistency across their preconceptions. Consistency is a product of the experiences unique to a practice. The background (or prejudices) of practitioners will therefore lead to unique insights about the morality of their practice and related phenomena. Accordingly, empirical ethics affirms that credible normative empirical data can be collected, challenged and refined by engaging with moral practitioners.

7.2.2 Practices and Empirical Ethics

To distinguish empirical ethics as a new approach to ethical analysis in which theory and insights from practice are seen as inherently complementary and open to revision, it is not enough to classify research merely linking empirical research with philosophical ethical analysis as empirical ethics (cf. McMillan 2008; De Vries & Gordijn 2009). Rather, to make the distinction meaningful the defining feature of empirical ethics must be the constant, often iterative relationship between empirical data and ethical analysis.⁷⁰ The relationship plays this central role because it collapses the distinction between descriptive and prescriptive statements in practice, also referred to in meta-ethics as the fact-value gap (De Vries & Gordijn 2009). A basic assumption of the iterative relationship is that descriptive and prescriptive approaches are complementary, meaning it is possible to gather empirical data with normative content. Taking this assumption one step further, the distinction between description and

⁷⁰ Implications for this distinction in defining the empirical ethics mindset compared to current practice are reviewed in Appendix 8.

prescription may disappear in the data and subsequent analysis, thereby collapsing the traditional division of labour between scientists and ethicists in social research.

7.2.3 Alleged Meta-Ethical Fallacies of Empirical Ethics

The classification of empirical ethics as an iterative relationship between empirical data and ethical theory suggests that description and prescription may not only be complementary, but cease to exist as a distinction in empirical ethics studies. Critics of empirical ethics are quick to point out two meta-ethical problems facing empirical ethics posed by this potential collapse: the is-ought problem and the fact-value distinction (McMillan 2008; De Vries & Gordijn 2009, p.196).⁷¹ Initial appearances suggest that empirical ethics derives normative conclusions from descriptive premises, meaning “empirical ethics would disregard the is-ought gap...and/or violate the fact-value distinction” (De Vries & Gordijn 2009) at the cost of its credibility. These ‘meta-ethical fallacies’ are the most common arguments against the use of empirical ethics.

7.2.3.1 Is-Ought Problem

The is-ought problem (or ‘Hume’s Law’), originally identified by David Hume in *A Treatise of Human Nature* (De Vries & Gordijn 2009, p.196), is often used interchangeably with the fact-value distinction. In practice, the two are closely related. According to Hume, the is-ought problem is a logical fallacy which occurs when inferring normative conclusions from facts alone (Hume 1978). As a logical principle, the is-ought problem asserts that any amount of descriptive information, or a description of what *is*, can never by itself be used to infer how things *ought* to be (Hume 1978).⁷² In other words, “moral judgments cannot be deduced from statements of fact, not because the former are moral and the latter nonmoral, but because the former are evaluative and the latter are descriptive” (De Vries & Gordijn 2009).

While the truth of this position in statements about social realities with implicit normative claims is questionable (cf. Searle 1964), it can nonetheless be avoided in practice through the

⁷¹ A third fallacy, the naturalistic fallacy, is mentioned by De Vries and Gordijn but its relevancy to empirical ethics is quickly (and correctly) dismissed. The naturalistic fallacy is not committed in empirical ethics as long as normative conclusions are not derived from uncritical moral beliefs of practitioners. In other words, the beliefs of practitioners are not taken at face value—it is the reasoning supporting beliefs and practices, subjected to scrutiny and refinement via dialogue and moral experiences, which is seen as a legitimate source of morality. As long as the moral beliefs of practitioners are not granted foundational legitimacy as the sole source of morality, as is the case in this project, the naturalistic fallacy is not committed. For a fuller discussion of the naturalistic fallacy see: (De Vries & Gordijn 2009).

⁷² The ‘is-ought’ problem is related to the ‘ought-can’ position, by which the prescription of a moral obligation to act in a certain way is only defensible if an actor can logically perform the prescribed act. For more on this, see: (Kant 2003).

combination of descriptive empirical data and normative premises. The fallacy only exists if normative conclusions are drawn from descriptive statements alone, yet Hume's account does not preclude the addition of an argument to the description, which leads to a normative conclusion (McMillan 2008, p.15). In the empirical component of the research project, normative premises, concepts and theories were offered in the interview by the researcher and (occasionally) the participant to clarify and refine normative claims and descriptions of the practice (see: Section 8.5.1).

While the is-ought principle is avoided in practice in this project, it is also rejected in principle. Acceptance of Hume's Law is dependent upon certain axioms of normative ontology, chief of which is that 'descriptions' cannot contain normative content. If normative descriptions exist, then it stands to reason that prescriptive statements can be deduced directly from them. Empirical ethics suggests that normative descriptions exist in the form of empirical data with normative content (see: Section 7.2.1). Beyond this, the is-ought problem is incomprehensible from a teleological approach to ethics; virtues are defined against social roles and practices with preconceived ends or a *telos*. It is therefore possible to evaluate something by making a descriptive statement; to use a famous example, it can be validly inferred from "He is a sea-captain" that "He ought to do whatever a sea-captain ought to do"; in fulfilling this social role, the man accepts a normative responsibility to act well in achieving the ends expected of him as a sea captain (MacIntyre 2007, p.57). Therefore, describing the man as a sea-captain is a description which also contains normative content—no further appeal is necessary to principles or duties which the captain may have violated to evaluate his behaviour. Evaluations of persons or objects which can be defined by a functional concept can therefore move from descriptive ('is') premises to normative ('ought') conclusions without appealing to further normative premises. The fact that the object, or person, can be described in terms of its functions, or social role, means it is more or less 'good' according to how well it fulfils that role, understood as its *telos* (MacIntyre 2007, p.58). From this perspective, the is-ought problem is seen as a relic of the confusion of the meaning and function of morality and its vocabulary which pervades moral discourse in recent centuries (MacIntyre 2007), and not as a valid logical fallacy in moral reasoning.

7.2.3.2 Fact-Value Gap

Despite the rejection of the is-ought problem in principle, it is important to also consider the meta-ethical implications of a mere avoidance of the problem in practice in case the principled

stance of the researcher is not accepted by the reader. While the practical avoidance of the is-ought problem is logically sound, it suggests that the fact-value gap is legitimate. The fact-value gap refers to the belief that the descriptive and normative content of empirical data, or descriptive science and ethics, can be cleanly separated into descriptive and normative parts (McMillan 2008, p.14). Fortunately, the fact-value gap is best thought of as a meta-ethical position rather than a logical fallacy, which reduces the importance of taking a conclusive stance on the gap.⁷³ Two versions of the gap exist: (1) that “no statement or concept is irreducibly” both descriptive and normative, or (2) that facts do not presuppose values, meaning science is value-free (De Vries & Gordijn 2009, p.198). The first version is best seen in “thick ethical concepts” and virtues, for example the terms “cruel” or “honourable” (De Vries & Gordijn 2009, p.198). Proponents of the gap hold that “cruel” has both descriptive and normative components which can be separated cleanly, meaning the concept “cruel” is used in two distinct ways (Leget et al. 2009; De Vries & Gordijn 2009). However, critics suggest that because cruelty has both descriptive and normative aspects, and because these aspects can be combined in a single concept, it must be irreducibly both descriptive and normative (De Vries & Gordijn 2009, p.198).

7.2.3.2.1 Criticisms of the First Version of the Fact-Value Gap

Critical of the first version of the fact-value gap, some empirical ethicists assert that empirical research can produce data that is inherently descriptive and normative (Molewijk et al. 2004; McMillan 2008, p.15), meaning the distinction between fact and value or descriptive and normative collapses within empirical research. An example of this type of data is the moral beliefs of practitioners which are based on interpretation of social processes and events, such as that collected in the empirical study (see: Chapter 9). In this type of data it is not clear where the line between descriptive and normative lies, as the interpretive process of developing understanding does not involve a clean separation of these two elements; nor is it clear why an attempt should be made to separate these elements at all in data with normative content. Understanding is developed through dialogue, in which normative claims, values and principles are critically examined to reach a fusion of horizons. Taken as a form of ethical

⁷³ It should be noted that the position one takes on the gap has implications for the legitimacy of the is-ought problem—if irreducibly complex concepts exist which are simultaneously descriptive and prescriptive, as is suggested by theories of virtue (e.g. (Darwall 2003; MacIntyre 2007), the is-ought problem would not apply to such concepts (see: Section 4.3.1). The classification of normative empirical data as such an irreducibly complex concept would therefore eliminate any worry about the is-ought problem.

analysis, it is unclear how the normative and descriptive aspects of the outcomes of dialogue (in this case, normative claims about future uses of PHM) could possibly be separated. If the first version of the distinction collapses, the is-ought problem is nullified because normative conclusions are not reached from descriptive statements alone; rather, the data being used to reach normative conclusions has inseparable descriptive and normative elements.

Attempts to maintain the legitimacy of the is-ought problem by separating physical sciences from social sciences are revealing in terms of the importance of resolving the fact-value gap for empirical ethics. One such attempt (Mackie 1980) which separates social reality from the external “objective” reality or structure upheld by scientific disciplines, claims that “social facts and human purposes are...implicitly normative” (De Vries & Gordijn 2009). Seen as a meta-ethical issue rather than a logical fallacy, it is unclear why empirical ethics needs to have a unified stance on the issue (De Vries & Gordijn 2009). Meta-ethics operates at the level of theory, yet empirical ethicists need only show that description and prescription are intertwined in practice to justify the iterative integration of empirical data and ethical theory in ethical analysis. Thick ethical concepts such as ‘cruel’ (MacIntyre 2007), virtues and empirical data with normative content all provide proof of this entanglement.

7.2.3.2.2 Criticisms of the Second Version of the Fact-Value Gap

The second version of the gap upholds the ideal of objectivity in the sense that scientific enquiry can lead to data and conclusions that are free from values. However, a critic of this version would argue that science is bound by its own values, in the sense that it relies on standards such as falsification to ground truth claims (cf. Popper 1959; Popper 2002). Critics can also assert that empirical data with normative content has a legitimate place in (social) science. Both of these versions of the fact-value gap are meta-ethical views rather than logical fallacies.

In recent years the assertion that science is value-free has been increasingly challenged by ethicists calling for new study designs and methods of data analysis in which empirical data is recognised as (implicitly) normative (Molewijk et al. 2003; Goldenberg 2005; Ives & Draper 2009; Kon 2009). Descriptive science claims to be value-free, yet the same cannot be said for social scientific data dealing with normative claims and moral beliefs, which is reliant upon interpretation framed by prejudices. Indeed, the elimination of interpretive bias sought in the

positivistic paradigm is seen as an inappropriate and hopelessly flawed ideal in hermeneutics research (see: Chapter 3; Schwandt 2000).

While the fact-value gap lies at the centre of an interesting meta-ethical debate, its resolution does not impact on the justification of empirical ethics and hence the research project, which is concerned with empirical data concerning social practices, normative claims and beliefs. Regardless of the meta-ethical position taken towards the fact-value gap *in principle*, the collapse of the gap in practice suggests that the separation into descriptive and normative parts in ethical analysis is unreasonable, overly atomistic and perhaps impossible (MacIntyre 2007; McMillan 2008, p.16).⁷⁴ Recognition of the entanglement of facts and values in hermeneutic dialogue is enough to justify the integrative approach taken to ethical analysis as well as application and revision of the conceptual framework.

7.2.4 Empirical Ethics and Uncertainty

Identifying the applicability of alleged meta-ethical fallacies to empirical ethics is important to justify the role given to the claims of moral practitioners in applying and refining the conceptual framework developed above (see: Chapter 4). While these fallacies cannot be conclusively disproved, arguments have been offered to show that the claims of moral practitioners possess initial credibility or justificatory power in moral decision-making, upon which theory can be built. The beliefs of practitioners can be treated in many ways in ethical analysis—as a legitimate source of morality, contextual information, specification of theoretical concepts, or evidence of the relative importance of ethical concepts—but their value is beyond question in empirical ethics. However, as the claims are uncertain in the sense that they describe potential futures, their initial credibility cannot be equated to that of claims describing existing practices or the correct course of action in an existing case (cf. Tannert et al. 2007; Brey 2011). In short, it is not yet clear how normative empirical data can contribute to truth claims about the future. It is therefore necessary to explore the problems caused by uncertainty for ethical assessment of emerging technologies which incorporates the views of stakeholders potentially affected by the technology into assessment.

⁷⁴ Examples of research undertaken under the moniker of empirical ethics which demonstrate the unavoidable collapse of description and prescription are reviewed in Appendix 10.

7.3 Uncertainty and the Ethics of Emerging Technologies⁷⁵

It has long been established that technologies can cause ethical problems (Dusek 2006). There is broad agreement that an early recognition of these issues may provide avenues to address them through anticipatory governance and design. A core issue is that a tension exists between the empirical and the normative dimension of dealing with future and emerging technologies. This is the heart of the Collingridge (1980) dilemma which states that it is impossible to know the consequences of an emerging technology at an early stage when it would be comparatively simple to change the technology's trajectory. Once the technology is more established and it becomes clearer what its social and ethical consequences are going to be, it becomes increasingly difficult to affect its outcomes and social context. PHM can be said to exist at a middle stage in the terms of the Collingridge dilemma—the characteristics and intended uses of the technology (in England) are understood, but it is not yet widely used. Despite the fundamental problems posed by the Collingridge dilemma, there continue to be attempts to better understand future technologies and to predict the ethical issues they are likely to raise with a view to addressing them early through anticipatory policy, regulations and design, all of which are aided by early development of concepts and theories which explain the potential implications of the technology.

There exists a rich history of attempts to develop epistemologically robust ways of understanding how emerging technologies will affect the future, for example in future studies or technology foresight (Cuhls 2003; Georghiu 2008). Such approaches often attempt to provide an empirical basis for policy makers due to a growing demand for evidence-based policy (Banks 2009). Despite this rich field of research, there is still no agreement on some of the conceptual underpinnings and the question of how our understanding of possible futures can or should be translated into theoretical insights or practical activities that will allow for the desirable shaping of future technologies.

At the heart of the conceptual disagreement is a common epistemological problem: predictions and anticipatory action are based on normative evidence with problematic epistemic status. This section seeks to address this problem from a Habermasian perspective

⁷⁵ Key ideas and wording of this section are taken from a forthcoming collaborative research paper on the epistemic value of normative claims about the ethics of emerging technologies under conditions of uncertainty. Bernd Stahl and Ben Fairweather of the Centre for Computing and Social Responsibility at De Montfort University are co-authors of the paper. The paper is currently under review for publication by Science, Technology & Human Values.

by arguing that researchers can base reasonable validity claims on the basis of normative empirical research on the ethics of emerging technologies while uncertainty still prevails, by treating claims about potential futures arising from empirical work in the same way as other contentious validity claims. Habermas' recent work on religion in public discourses is used to argue that normative claims about the future might count in a similar way to religious claims. This allows the incorporation of uncertain normative claims into ethical analysis of emerging technologies.

The importance of the epistemic value of uncertain normative claims lies in the reliance of anticipatory action on moral justification. To be justifiable, anticipatory decisions require a legitimate source of morality, as determined by the relationship between current and ideal practice, or facts and norms. Conceptualising the appropriate interaction between facts and norms is a core problem of ethics and by no means novel. According to the empirical ethics mindset, the introduction of normative empirical data into ethical analysis is appropriate. While empirical ethics has contributed to this debate within research into current practices, it has not yet turned its attention to the unique epistemic challenges presented by future practices or emerging technologies. If empirical ethics is to be adapted to provide 'evidence' or a legitimate source of moral justification for theory building and anticipatory actions, the epistemic value of its uncertain normative claims must be made explicit.

7.3.1 Methods of Emerging Technology Assessment

To understand the problems caused by uncertainty, it is illuminating to consider how anticipatory governance actions to prevent ethical issues for emerging technologies are prescribed in support of normative empirical data of questionable credibility. Even though improvements to governance are not sought in this project, the challenges faced in these approaches help explain the challenges of uncertainty. These challenges are identical to those faced in justifying the refinement of the conceptual framework on the basis of normative empirical data of uncertain credibility. Of the approaches prevalent in recent decades, the Precautionary Principle and Technology Assessment are perhaps the best known. In understanding the challenges, it is important to note the difference between uncertainty and risk, and how the concepts affect the reliability of predictions of the future.

7.3.1.1 Uncertainty

With uncertainty the probabilities of possible outcomes are unknown, whereas with risk “the probability distribution...is known or predictable” (Ahmed & Skogh 2006). In looking at technologies still under development, researchers are often faced with uncertainties for which even the minimal data required for the maths of imprecise probability is unavailable (Tannert et al. 2007). With this said, the paradigmatic case considered here (PHM) is a technology that is sufficiently developed for meaningful discourse to be possible about the nature of the technology and its initial uses, but where there is still uncertainty about its future implications. Under this type of uncertainty regarding future technologies, one can ask on which grounds theoretical and practical decisions can be made and justified, or how uncertain normative claims can be treated as credible.

Uncertainty exists regarding the future consequences of emerging technologies because, in opposition to ‘technological determinism’, technologies are not fixed entities with predetermined outcomes (Stahl 2011b, p.97). Rather, the effects of a technology within a given context are as dependent upon the actors and features of the context, as on the characteristics of the technology itself (e.g. Sections 3.3.2.1 and 3.3.4). In this setting, uncertainty is a product of the interactions between complex systems (society and emerging ICTs) with nonlinear behaviour, which precludes prediction of outcomes through “deterministic reasoning and/or research” (Tannert et al. 2007, p.893). This implies that descriptions of the future must be seen as predictions lacking certainty, although methods are required to separate credible predictions from wild fantasy.

7.3.1.2 Technology Foresight

One such method is technology foresight (Cuhls 2003). Ethical assessment of emerging technologies requires a way of sorting predicted technologies from emerging ones, or those which are merely imagined from those that will likely be developed in the future. Although “no absolute truth claims about the future are possible,” more or less credible predictions of possible futures can still be made. To make credible predictions, foresight research abandons a deterministic view of a single possible future, focusing instead on the different pathways the future may take based upon actions in the present (Stahl 2011d, p.63). Desirable futures can be separated from undesirable ones, while identifying recommendations for how to bring about the former. Short of predicting possible futures with certainty, foresight research is seen to provide the following basis for assessment of emerging technologies:

- “To enlarge the choice of opportunities, to set priorities, and to assess impacts and chances
- To prospect for the impacts of current research and technology policy
- To ascertain new needs, new demands, and new possibilities as well as new ideas
- To focus selectively on economic, technological, social, and ecological areas as well as to start monitoring and detailed research in these fields
- To define desirable and undesirable futures
- To start and stimulate continuous discussion processes” (Stahl 2011d, p.63).

While not a methodology of ethical assessment of emerging technologies as such, foresight research prescribes norms by which desirable future states may be identified, and creates empirically informed descriptions of possible futures as influenced by current decisions and actions (Cuhls 2003). Foresight research therefore provides a foundation upon which ethical assessment may occur. PHM-Ethics and ETICA (see: Chapter 1), conceived as examples of foresight research, along with the findings of the literature reviews (see: Chapters 2 and 3), provide a basis for this project by describing current technological developments and potential implications. In other words, foresight research provides reliable descriptions of the future, so far as they are possible, so that anticipatory ethical assessment of emerging technologies may occur while uncertainty still prevails.

7.3.1.3 Uncertain Normative Claims

In the context of ethical assessment of emerging technologies, uncertain normative claims are contentious arguments which describe the appropriate response to future social and ethical impacts of emerging technologies, or what “should” be done in the future. Normativity refers to any declaration with prescriptive or evaluative content, including statements of moral evaluation (such as “this technology is good”) or prescription (such as “one should do ...”). As the future is inherently uncertain⁷⁶, the claims are not epistemologically equivalent with claims based upon existing social practices (cf. Widdershoven, Abma, et al. 2009) or empirically observable phenomena (cf. Popper 1959).⁷⁷ If uncertain normative claims are to be employed in future-oriented ethical assessment, an alternative account of their epistemic value is required which acknowledges the inherent uncertainty of the future.

⁷⁶ For an explanation of how certainty is derived from validity rather than credibility, see Appendix 11.

⁷⁷ How validity derives from scientific observation is contentious question. Here, Popper’s critical rationalist position, in which all scientific knowledge is provisional and held up to the standard of falsification, is adopted. Certainty, then, refers to the falsifiability of a scientific hypothesis or theory.

7.3.1.4 Evidence-based Decisions under Conditions of Uncertainty

In the past, the difficulties of predicting the future (uncertainty) have been addressed through the creation of decision rules, which guide decision making in absence of reliable empirical or statistical data concerning risks and impacts. A notable early decision rule was the ‘rule of insufficient reason’ (“Laplace rule”) otherwise known as the ‘principle of indifference’ – that when we are too unsure about the probability of possible outcomes “we should treat them as if they were equally likely” (Sinn 1980; Goodin 1983, pp.165–6). This has been shown to be inappropriate in very many circumstances; subsequent research has advanced on decision rules at varying levels of uncertainty in a number of ways, resulting in a “vast literature” (Ahmed & Skogh 2006, p.184) including, for example the ‘diversification theorem’, which explains why it may be wise to spread investments over a number of assets when the returns are uncertain.

The uptake in research reflects the ongoing debate about decision rules under conditions of uncertainty, largely provoked by debates about policies for new technologies, and especially environmental policies during the late 20th and early 21st centuries. A clear understanding of the epistemic value of uncertain normative claims becomes necessary to distinguish between credible and fanciful uncertain claims about the potential ethical implications of emerging technologies, and in developing theoretical understanding and practical anticipatory actions in response. Opponents of regulation have time and again argued for a position that has been characterised (Wagner 2003, p.77 n.60) as saying that regulation should not occur because there is “not enough science to justify protective regulation.”

In response proponents of regulation no longer rely entirely on trying to provide scientific proof that will satisfy their opponents. Sometimes this is because “standards for the requisite evidence are never articulated” (Wagner 2003, p.77 n.60) and thus never met to the satisfaction of opponents of regulation. Even without scepticism towards the tactics of opponents of regulation, proponents may have realised that requiring scientific proof of harmful relationships to justify regulation is inappropriate. There are two fundamental reasons for this. The first is the epistemic status of science: scientific theories are, fundamentally, provisional (awaiting falsification) (Popper 1959), so conclusive evidence to justify regulation would forever remain out of reach. The second is because of the conservatism of science: in identifying relationships science does not work on the basis of balance of probabilities, but rather seeks to “minimise ‘false positives’”, even though in doing

so its “procedures increase the chance of ‘false negatives’, that is, failing to assert that there is a relationship when there is a relationship” (John 2010, p.5). Rather than always seeking to provide scientific proof that will satisfy opponents, proponents of (for example) environmental regulation have looked for arguments that regulation should begin before there is certainty about the harmful effects of the processes they want regulated; in other words, they seek anticipatory decisions under conditions of uncertainty.

7.3.1.5 *The Precautionary Principle*

Taking a leading position among these approaches is the Precautionary Principle (PP), which came to global prominence with the Rio Declaration of 1992 (UNCED 1992). Although a common definition is lacking (Gardiner 2006, pp.34–5), the core content of the PP is found in the Wingspread Statement (Wingspread Statement 1998) about environmental impacts of human activity:

“When an activity raises threats of harm to human health or the environment, precautionary measures should be taken even if some cause and effect relationships are not fully established scientifically.”

From its creation the PP has had a severely poor philosophical reputation (Gardiner 2006, p.33; Hughes 2006, pp.448–9, 463), although recent adaptations have sought to improve its standing. The poor philosophical reputation comes largely from the “paradox of precaution” (Morris 2000; Tannert et al. 2007). The “paradox of precaution” arises if the PP is interpreted as saying that we must avoid harm by eschewing risky, but potentially beneficial technologies. Under this interpretation harm arises since the benefits of adopting the technologies are foregone with “for example... lost opportunities to prevent disease and death”, resulting in a “precautionary principle [that] would instruct us to refrain from implementing itself” (Hughes 2006, p.449). Beyond this, even enthusiastic advocates have been willing to accept it is “ill-defined and imperfectly translatable into codes of conduct” (Jordan & O’Riordan 1999, p.15). Recent works (cf. Gardiner 2006; Hourdequin 2007; John 2010) have produced more philosophically robust formulations, which may give valuable guides to action in certain circumstances. Gardiner’s (2006, pp.47–8) work turns on criteria for the employment of the PP. A key insight from Gardiner is that the PP applies in conditions of uncertainty, but not when ignorance exists of the range of outcomes over which there is probabilistic uncertainty.

Unfortunately, the PP lacks a mechanism for identifying and normatively assessing potential outcomes. Such an “identification mechanism,” guided perhaps by normative empirical research, would help identify possible outcomes under conditions of uncertainty. Approaches to the ethical assessment of emerging technologies, including PHM, require such a mechanism which involves cross-referencing “descriptions of the technology...with ethical values and principles” (Brey 2011). Identification mechanisms therefore not only identify a list of possible ethical outcomes, but give normative content to these outcomes by locating them within existing ethical theories and concepts. The interplay between facts and norms can be said to exist in this process which relies upon normative empirical data. Without such a mechanism the PP is of little use in evidence-based policy making and the ethical assessment upon which it is based, if only because it fails to explain how decisions should be made, or how to relate uncertain facts and norms in ethical assessment.

7.3.1.6 Technology Assessment

Descriptive and prescriptive information relating to the potential outcomes of emerging technologies is required to use the PP in decision-making. Such information can be gathered in empirical ethics research, in which normative claims are made about emerging technologies. Of the approaches capable of collecting, analysing and applying such information under conditions of uncertainty, TA is perhaps the most widely used. TA is a field which studies and evaluates the interaction between new technologies and the environment, industry and society (Tran & Daim 2008). Similarities are found with other plausible approaches for responding to emerging technologies including participative design (Mumford 2003), value-sensitive design (Friedman et al. 2008) and other socio-technical approaches (Sandberg 1985).⁷⁸ Studies engaging in TA often work on “known or potential applications” of emerging technologies as well as future and technological forecasting studies (Cagnin et al. 2008; Georghiu 2008; Brey 2011). Crucially, TA includes an “identification mechanism,” a normative interest in future technologies, and a range of empirical methods to pursue this interest.

⁷⁸ It is worth noting that participatory TA (pTA) (cf. Joss & Bellucci 2002) has been recognised as an appropriate research methodology to respond to the uncertainty of emerging technologies. Briefly, the benefit of pTA is the involvement of stakeholders who will be affected by the emerging technology in the near future. Stakeholder involvement moves from reactive to proactive ethical assessment by anticipating impacts of the emerging technology according to ‘local knowledge’ (Stahl 2011b, p.104), or the context-specific values and experiences which will shape the moral character of future contexts of use. Local participation therefore improves both normative insights into the technology, and the practical acceptability of proposed regulations and solutions to predicted effects. The combination of empirical and theoretical approaches taken in this project shares these benefits related to proactive ethical analysis.

The field emerged in response to experiences of undesirable or unintentional side effects of emerging technologies (Grunwald 2009). TA comprises a family of approaches that aim to combine empirical research on likely consequences of technologies with normative insights. Its various flavours, including participative TA (van Eijndhoven & van Est 2002; Joss & Bellucci 2002) and constructive TA (Genus & Coles 2005), employ a broad array of methods which include participation from a variety of stakeholders, most notably laypersons as representatives of future users of the technologies in question.

By anticipating and responding to the challenges presented by emerging technologies during the development and early deployment cycles, TA studies aim to guide the development and regulation of technology in more desirable directions (Brey 2011). TA is united as a field by its emphasis on the production and evaluation of knowledge concerning social, economic and environmental impacts for the purpose of providing recommendations to steer the social response to emerging technologies.

7.3.1.7 Problems of Normative Evaluation in TA and the PP

TA studies often refer to the PP in making recommendations for social response to the uncertainties of emerging technologies (Grunwald 2009, p.1108). This situation creates a problem for TA as most versions of the PP lack guidance on how to balance contradictory uncertain normative claims. The reliance on such an ambiguous decision rule may be a conscious decision—the social response must surely be sensitive to the context in which the technology will be used, which will influence the relative value of normative claims. Still, accepting this limitation of the PP ignores a common problem of any approach to the assessment of future technologies. Even if normative assessments give importance to context (which they should), there must be evaluative criteria by which the relative value of (uncertain) normative claims are determined. While these criteria may change according to context, culture, religion, ethical viewpoint and so on, the need for an evaluative mechanism does not go away. Balancing competing claims without knowledge of their epistemic value is akin to judging the scientific merit of a controlled trial without an understanding of how controls contribute to the scientific method (cf. Popper 1959)—the key piece of knowledge for determining the relative value of uncertain normative claims, their epistemic status, is missing.

This problem with ethical assessment of potential futures created by emerging technologies applies equally to the development of theoretical insights into the technology such as the

conceptual framework—a mechanism is needed to determine the relative credibility of normative explanations of the future, or those which say the future ‘should’ be a certain way based on an uncertain description of it. Without such a mechanism, it is unclear how to separate more or less ‘right’ or credible empirical data in determining whether the conceptual framework helps explain the ethical implications of the future, and in identifying its limitations in doing so. Practitioners make claims about their attitudes towards potential futures, which are fundamentally uncertain because they are based in unreliable descriptions of the future, and how they will react to it at a future time. A mechanism is required to make sense of these two forms of uncertainty in such a way as to allow proactive theory building based on normative empirical data from anticipatory empirical research.

7.3.1.8 The Importance of Epistemology in Anticipatory Action and Theory Building

To return to the original problem identified in this section, emerging technologies such as PHM can raise ethical issues that ethicists, policy-makers, developers and civil society would like to address proactively. Being situated in the future gives such technologies uncertain outcomes. Despite this, empirical research is still conducted to determine the possible outcomes and norms which should guide future uses, development and regulation of the technology. However, as a result of the uncertainty of the future, such normative empirical research requires a different type of truth claim compared with objectivist research in the natural sciences, which bases truth claims in validity measured in terms of falsifiability (Popper 1959). While decision principles such as the PP can give some indication of appropriate evaluative mechanisms, these only take effect once stakeholders in decision-making agree upon a shared view of facts and norms. TA and related approaches set out to provide empirical input into such policy development and decision mechanisms. However, the question of the epistemological evaluation of the outcomes of TA and similar empirical research remains open, which precludes a shared foundation of facts and norms on which normative evaluation may occur. In terms of the conceptual framework for PHM built here (see: Chapter 4), this problem means that the results of the empirical study cannot and should not be considered in refining the conceptual framework until their relative epistemic value is understood. In the following section it is suggested that their value can be determined through ‘translation’ as described in Habermas’ discourse ethics.

7.3.2 A Reconciliation of Norms, Facts and the Future: Discourse Ethics and the Interpretation of Uncertain Normative Claims

The relationship between 'is' and 'ought', the way in which empirical ethics deals with this relationship, and the broader context of ethics under conditions of empirical uncertainty have been considered thus far. The purpose of considering these topics is to develop a sound theoretical basis that can be used to reconcile empirical research and normative aspects of emerging technologies. For this purpose it now needs to be shown that the different aspects under consideration can be combined in a theoretically satisfactory manner to provide a coherent account of the epistemic value of normative empirical claims under conditions of uncertainty. There are, no doubt, numerous ways of providing such theoretically sound conceptual foundations. In terms of epistemic value, uncertain statements concerning normative aspects of emerging technologies can be treated analogous to religious statements which, according to Habermas (2008; 2011), should be included as legitimate interventions in public discourses. This is not to say that uncertain normative claims and religious statements share similar foundations (e.g. faith, superstition), but rather that both possess inherent uncertainty which must affect how they are treated in discourse. Certainty refers here to the possibility of falsification of the claim and its evidence base. Uncertain normative claims are characterised by reliance upon descriptions of the future which are inherently uncertain, whereas religious claims rely upon faith or belief beyond empirically observable phenomena.

One appropriate way of providing the necessary theoretical underpinnings for normative research on emerging technologies is to make use of existing work on discourse ethics. The rationale for this choice is that discourse ethics is a well-established procedural approach to ethics (Edgar 2002, p.45) that deals with the relationship between normative and empirical statements. Discourse ethics furthermore has an established track record of being applied to (human interaction with) information systems (Mingers & Walsham 2010). Finally, recent developments in the broader political discourse theory as put forward by Habermas allow for the incorporation of statements that lack the epistemic certainty that can be expected in statements about empirical observations of existing phenomena (e.g. Habermas 2008; Habermas 2011).

7.3.2.1 Discourse Ethics as a Theoretical Foundation for Empirical Ethics under Uncertainty

The term 'discourse ethics' was originally coined by Karl-Otto Apel and was adopted and developed by Jürgen Habermas (Edgar 2002, p.44). The Habermasian version of discourse ethics is used here. Discourse ethics must be understood in the broader context of Habermas' TCA (Habermas 1984; Habermas 1985) (see: Section 6.1.3.3.1). Claims in communication are structured by three validity claims: truth (Wahrheit), rightness (Richtigkeit) and authenticity (Wahrhaftigkeit). In terms of encountering uncertain claims, the TCA indicates that **there is no fundamental distinction between normative and descriptive statements**. Any statement can raise validity claims relating to truth, normative rightness and the speaker's authenticity. All validity claims are subject to discursive questioning.⁷⁹

Habermas' discourse ethics incorporates these principles of the TCA and uses them to develop an explicit ethical theory (Habermas 1992; Habermas 1993). Discourse ethics is expressed in two basic principles, the discourse principle and the universality principle. The discourse principle states that only those norms can claim to be valid that meet (or could meet) with the approval of all affected in their capacity as participants in a practical discourse. The universality principle goes beyond acceptability to the affected and states that the consequences and side effects arising from the general adherence of a norm have to be acceptable for all involved stakeholders and, ideally, for everybody (Habermas 1992, p.65).

Individuals are stakeholders in a discourse when the outcome of that discourse affects their interests. The boundaries of the definition of those 'affected by' a practice can be extended indefinitely; in the case of hospice care, developers, friends, taxpayers, government, civil society and future patients could be 'affected by' hospice care in a national healthcare system. However, moral practitioners are stakeholders involved in the day-to-day activities of a practice, or those who have 'moral experiences' specific to that practice. Moral practitioners can contribute normative claims with initial credibility to a discourse based on relevant experiences in the practice concerned (see: Section 7.2.1). For this reason moral practitioners are sought to participate in the empirical study, conceived of as an ethical discourse.

As a procedural approach, discourse ethics does not prescribe moral truths, but rather describes a procedure for communication which arrives at moral truths. Agreeing upon claims

⁷⁹ By the vocabulary used Section 6.3.1, validity claims are a type of credibility claims.

fulfilling standards of validity in discourse brings participants closer to justified actions, or moral truth (Habermas 1984, pp.99–100). Despite the ‘universality’ of the method, rational discourse can produce local agreements understood as ‘true’ only within particular contexts or practices (Mingers & Walsham 2010, p.844), similar to MacIntyre’s practice internal goods (see: Section 4.3.1), making discourse a plausible model for applied ethical analysis. To arrive at any agreement, discourses need to resemble as closely as possible the “ideal speech situation,” a model for perfect discourse, in which all participants are allowed free and equal participation, questioning and introducing claims in the discourse. The discourse can be distorted through strategic action, coercion of participants or claims to truth by social position or rank (Habermas 1992, p.86). Habermas intends the ideal speech situation to be a “normative guide rather than a practical reality” (Jones 2001, p.70), although the requirements of ideal discourse are taken to be “presuppositions of rational argument itself” (Mingers & Walsham 2010, p.840), meaning by entering the discourse participants are bound by the logic of rational argumentation to adhere to its ideals in the search for truth. It is not meant to be operationalised to create ideal discourses; rather, it is an ideal framework of communication against which actual discourses can be criticised to reveal “systematic distortions, ‘ideology’ or ‘false consciousness’...[or] distortions of communications by powerful groups” (Jones 2001, p.70).

The value of discourse ethics with regard to ethical assessment under conditions of uncertainty is that it overcomes the limitations of the ‘is-ought problem’ and provides a theoretical position that enables empirical ethics research. **The discourse and universality principles provide an evaluative mechanism for normative as well as empirical interventions** (see: Section 6.1.3.3.1). To design interventions, practical discourses are required which support the voicing of empirical observations as well as normative positions.

7.3.2.2 Uncertain Normative Claims in Discourse

According to the TCA any validity claim can be queried, and then needs to be defended using good arguments in a discourse. This raises the question of how to evaluate and defend statements about the future that are fundamentally uncertain.

Within the framework of discourse ethics and the TCA at least two strategies are possible. One can use a methodological argument that defends statements with reference to the credibility of the methodologies that were employed in arriving at the statements. A statement about an

expected social or ethical consequence arising from an emerging technology could thus be defended by explaining the methodological approach that led to it. This is a rational way of dealing with the uncertainty of the future but it has the disadvantage that it can turn discourses about the ethical aspects of emerging technologies into discourses on methodologies for researching the future.

Recent work by Habermas (2008; 2011) points to a better way of incorporating uncertain normative claims into ethical discourse and anticipatory decision-making by treating uncertain normative claims as analogous to religious beliefs. The relationship between the two is that they occupy similar epistemological territory. Both types of claims rely upon or describe states of existence that are logically unknowable—metaphysics for the former, the future for the latter. As a result, neither can be falsified or tested through scientific observation.

The motivation for Habermas' interest in religious claims was the result of the continuing prevalence of religious interventions in modern political discourses and the recognition that these interventions must be taken seriously because they can be strong motivators of political action and the basis of legitimate democratic positions. Habermas' question is how a post-metaphysical nation-state, or a state that is not based on religious convictions or traditions, can react to and incorporate religious positions. He argues that such a post-metaphysical state needs to be secular and neutral towards religious convictions, in order to facilitate the peaceful co-existence of different, possibly contradictory religious positions. Religious citizens in a secular state have **a duty to translate their religious positions into a secular form** (Habermas 2008; Habermas 2011). At the same time, non-religious citizens have the duty to accept that religious positions can be rational and have a right to be heard. There is thus the possibility of a discourse despite the fact that some participants do not share the basic premises of the interventions recommended by others. This view can be interpreted as the implementation of the principles of the TCA in cases of principled disagreement over validity claims contained in statements made in the discourse.

This principle can be extended to cover uncertain normative claims arising from empirical work on future technologies. Such statements do not have the same epistemic status as statements about empirically observable phenomena. At the same time, they carry meaning and initial credibility where participants are involved in relevant associated practices (see: Section 7.2.1), and may fruitfully contribute to ethical-political discourses that shape the development of such

technologies. What is required from the different participants is (a) the ability and willingness to translate these uncertain normative claims into practically relevant statements and (b) the willingness by participants who doubt the credibility of such claims to listen to the translation in the attempt to use discourse to come to a better shared view of the social reality in which the discourse participants find themselves.

7.3.2.3 *Translation*

To make rational discourse possible by this account, participants in a discourse have a duty to translate uncertain claims into terms that can be understood by participants not sharing their basic premises, such as religious belief. Translation requires the reconstruction of uncertain normative claims into '**legitimate normative claims**', which are **comprehensible** and **acceptable** to participants and stakeholders in discourse (cf. Habermas 1975, 108). Normative claims about future states are vulnerable to propaganda, misinterpretation of evidence, faulty reasoning and ignorance. Accordingly, it would be foolish to apply a kind of 'Laplace rule' and view all uncertain claims as equally valid without further analysis. Two steps are necessary to translate such beliefs into legitimate normative claims that can be subjected to discourse. First, the justificatory evidence base upon which uncertain normative claims are constructed must be understood so formative experiences, flaws in reasoning or false statements can be identified. Second, the 'normative truth content' of uncertain normative claims must be understood. To unpack this concept, it is helpful to review Habermas' position on the utility of religious beliefs within a secular political society. Much as religious beliefs may rely upon adherence to questionable comprehensive doctrines, uncertain normative claims may be founded upon indefensible or selfish premises. However, both types of beliefs may contain legitimate conclusions or 'normative truths', albeit by reliance on questionable premises. Translation identifies the normative truth of questionable beliefs and translates it into an acceptable claim by, in the case of religious beliefs, translating it into secular terms or, in the case of moral beliefs, relating it to moral arguments, ethical concepts or principles, or empirical evidence seen as legitimate by other participants in discourse. This allows the different participants to agree or disagree on the content of the claims on the basis of mutual understanding, rather than rejecting uncertain claims outright due to a lack of shared basic premises such as religious belief or agreement on the shape of the future.

The translation of uncertain statements is the key to considering uncertain normative claims about emerging technologies as credible in ethical analysis and refinement of the conceptual

framework. Translation plays a critical role in ethical assessment under conditions of uncertainty clarifying the epistemic value of uncertain normative claims. To adhere to ideals of rational discourse, participants are required to translate their uncertain claims into terms understood by other participants by relating claims to shared premises, beliefs or evidence. The premises, evidence and conclusions which constitute the uncertain claim can be assessed during translation to identify the pieces of a claim which rely upon uncertainty, facilitating questioning of particular validity claims rather than the uncertain claim as a whole. In this way the normative truth content of uncertain claims is separated from the uncertain framework in which it resides. It is the act of separation which constitutes translation—a claim is broken down into its constitutive parts which are acceptable and comprehensible to stakeholders for further assessment in discourse. Translation thus allows for uncertain claims to be questioned in two different ways in discourse: first, are the uncertain descriptions of the future plausible given current empirical evidence and indications of the shape of the future?⁸⁰ Second, are the normative position which rely upon the uncertain descriptions of the future themselves acceptable to stakeholders, apart from the uncertain elements of the claim?

In a sense, claims are turned into ‘if-then’ statements: if a certain state of affairs occurs in the future, then (credible) prescriptive statement X is applicable. By separating claims into two (or more) constitutive parts, the validity of each can be considered separately in discourse. Discourse can then reveal incomplete, poorly supported or otherwise deficient uncertain claims, while refining and strengthening claims with a credible empirical or normative foundation. The importance here is on translation as a *process* in which uncertain claims are separated into premises for further assessment, rather than as a set of universal *criteria* by which uncertain claims are proven certain. Stakeholders bring into discourse various criteria for questioning and accepting the truth of a statement. Translation is the process which allows for these diverse criteria to be applied to uncertain claims in discourse, by separating the normative truth content of the claim from its uncertain framework.

This raises a number of follow-up questions, such as—what constitutes a successful translation?⁸¹ Who needs to translate what and to which degree? How does translation occur

⁸⁰ Criteria to determine credible predictions of the future will vary among stakeholders in discourse and between disciplines. The determination of acceptable criteria in this regard is a separate issue from establishing the need for and process of translation.

⁸¹ To the author’s knowledge, a ‘methodology of translation’ does not yet exist. Habermas has not elaborated the concept or provided examples of successful translations.

in practice? Multiple credible answers may exist to these key questions. A more fundamental issue is that it remains to be seen how the legitimacy of the evidence base and normative truth content of uncertain claims should be judged. Standards of legitimacy are required to determine if a translation has been successful.

7.3.2.4 Standards of Legitimacy

With an answer now posed to the epistemic problem posed by normative claims about the future, the problem turns to working out the standards by which translation can be deemed successful. This area has not been elaborated upon by Habermas, so the usefulness of translation as a method for establishing the credibility or unpacking the normative truth content of uncertain normative claims is still in question. As hinted at above, standards of legitimacy refer not to the ‘truth’ of uncertain claims, but rather to the quality of the process in which claims are questioned according to the diverse criteria of truth brought to discourse by stakeholders. The ideal of rational discourse is instructive in working out the requirements for successful translation. As previously mentioned the TCA identifies three types of ‘validity claims’ which arise in discourse, which operate as standards for judging the truth of a statement, or “norms of conduct” (Bauman 1978, p.241) (see: Section 6.1.3.3.1).

For validity claims to be questioned in a non-deceptive discourse, the statements of participants must be communicated intelligibly to other participants; this is a minimum requirement of the logic of rational argumentation (cf. Mingers & Walsham 2010, p.840), meaning participants entering the discourse are bound to communicate claims so they can be questioned fairly. The form in which statements are communicated is linked to the identification of “generalisable interests,” or those found rational according to the developing interpretation in discourse (Habermas 1975, p.108). For such communication to occur, statements must possess a basic level of comprehensibility so as to be understood, if not agreed upon (or found rational) by participants in the discourse. The communication of statements demonstrates the two step process by which statements enter and are queried in a discourse: they must first be communicated in a comprehensible manner before their validity can be assessed. This distinction between validity claims and the proceedings of discourse remains useful. Through this distinction the **credibility** of a claim in discourse can be separated from its **legitimacy**, understood as its acceptability and comprehensibility to participants when presented in a discourse.

The success of translation is determined by the **legitimacy**, and **not the credibility**, of translated claims.⁸² Judged in terms of legitimacy, translation allows for a plurality of moral beliefs while leaving judgment of the credibility of any particular belief subject to further discourse. Legitimacy refers to the comprehensibility and acceptability of claims in discourse—are the constitutive parts of the translated claims able to be understood and further assessed in discourse? Comprehensibility refers to whether participants are capable of understanding a claim based upon how it is expressed in the discourse. Acceptability refers to the expression of the claim in a vocabulary (terms, concepts and values) shared by the participants in the discourse, which allows for mutual understanding of the normative content of the claim and, therefore, fair discourse.⁸³ Acceptability **does not** relate to agreement on the validity of a claim. Translation is not merely an exercise in deconstructing statements, but requires translating a claim into pieces understood within the frames of reference of the stakeholders in a discourse. Standards of legitimacy must therefore ensure that claims are translated in such a way that they are comprehensible and acceptable to individuals coming from myriad theoretical and personal backgrounds.

A claim can only be queried and taken seriously in discourse once shown to be legitimate (Habermas 1975, p.108), or comprehensible and acceptable to its participants. For ‘certain claims’, legitimacy can be derived directly from validity. In the case of ‘uncertain claims’, legitimacy can be established through translation. In both cases the epistemic value of the claim is derived from its legitimacy, but in the latter the extra work of translation must be undertaken to demonstrate the legitimacy of the uncertain claim.

7.3.2.5 Translation in Practice

Uncertain normative claims regarding the ethical implications of emerging technologies contain three overlapping parts, each of which can be questioned in discourse. Consider the statement made by a daughter caring for her mother with dementia when asked about GPS tracking: “I wouldn’t feel comfortable putting a GPS tracking chip under the skin of my mother in the future. I would feel like I was spying on her. I know she would hate it because she is a very private person.” In this example, the following three types of claims are evident:

⁸² As a reminder, Habermas’ ‘validity claims’ are understood as an evaluation of credibility, not validity, in the terms used here.

⁸³ Of course, the vocabulary used in discourse must not merely consist of shared words and phrases, but meaning as well. While identical meaning is impossible according to hermeneutic ontology, it can still be pursued as an impossible ideal. Participants can attempt to understand and discuss the meaning of shared terms, concepts and values to others through dialogue.

1. **Characteristics of the Future**- The technological characteristics, capacities or uses of the technology in the future the respondent believes will occur, e.g. “GPS tracking chip under the skin.” These are descriptive statements of possible futures which can be evaluated for accuracy in light of technological forecasting studies, development trends and the political values or strategies which are intended to be met by using the technology. This component describes how the future will be, or what kind of technologies will emerge, based on ‘evidence’ available to the interlocutor.
2. **Reaction** – The respondent’s reaction to a particular use, e.g. “I wouldn’t feel comfortable...I would feel like I was spying on her.” These are local concerns and reactions based on perceived uses, and cannot be disproven initially because only the respondent is capable of saying how she will react (however, in due course these claims can prove false if the respondent reacts differently than she expected once the technology is experienced). Where a reaction is based on implausible futures or misunderstanding of the capacities of the technology, the respondent can be prompted to amend or clarify the reasoning behind their reaction.
3. **Values** – The moral beliefs or values which ground and explain the reaction, e.g. “I would feel like I was spying on her...she was a very private person.” Here the respondent is claiming that ‘spying’ is wrong, in part because her mother is entitled to some degree of privacy. This part of the statement expresses evaluations of right and wrong, alternative conceptions of morality and ethical values. The movement from values or conceptions of morality to a reaction and normative claim can be critically questioned.

This model of the structure of uncertain normative claims reveals how translation can be put into practice in analysing normative empirical data. Parts 1 and 2 are the source of uncertainty in normative claims about the future—is the respondent’s description of the future plausible? Would interaction with the technology change how the respondent reacts to it (by changing her values)? Parts 2 and 3 constitute the normative truth content of an uncertain normative claim—so long as the description of the future in part 1 is credible, the reaction to it in part 2 based on the values evident in part 3 must be taken seriously in discourse. In other words, assuming part 1 is correct or at least plausible based on (for example) technological forecasting or current development, parts 2 and 3 create a legitimate normative claim that can be treated as equivalent to other types of normative claims about the present.⁸⁴

Some consistency can be seen between current and future technologies in terms of their normative dimensions. For instance, fear related to privacy violations resulting from inappropriate sharing of data are equally applicable given current and future technological capacities. This consistency can thus be used as a basis to judge the future claim as legitimate;

⁸⁴ This argument for legitimacy is similar to the ‘basing requirement’ in coherentist approaches to moral justification, according to which “a person’s beliefs [should] be based in an appropriate way on her evidence, if the beliefs are to count as justifiably held” (Sayre-McCord 1996, p.14).

if the future incident were to occur today, would the normative claim be justified? In this case, the temporal aspect of the incident becomes more or less irrelevant in terms of the credibility of the claim. While the future incident will undoubtedly have a unique character or degree of seriousness (e.g. much more sensitive data may be at risk in the future due to PHM), and the user's values or attitudes towards the technology may change over time from exposure to it (cf. Latour & Venn 2002), the consequences of the privacy violation can still be understood initially and expanded upon in understanding the normative importance of the claim about the future.

For the three component parts to be open to discursive questioning, translation requires interpreting claims with due regard to frame of reference of participants in the discourse, so as to ensure the meaning of the concepts and terms employed in the translation are shared as far as possible (recognising that identical meaning is impossible). To be successful, the translation must not only emphasise features deemed relevant or important by the translator, but explain these features using a frame of reference (language, culture, history, concepts) that are familiar to the interpreter. As Habermas explains, the translation of religious beliefs in secular political discourse must discard controversial features such as "faith" and "miracles" which are unlikely to be considered relevant or important by members of society which do not share cultural consistency with the person making the claim (Habermas 2011). The same can be said for uncertain claims made on the basis of foundational beliefs, rumours, misunderstanding of the capacity of emerging technologies, or perceived uses with little empirical support from foresight studies, policy positions, or other indicators of future contexts.

This account clarifies the components of an uncertain normative claim which are being questioned in discourse based on the TCA's three validity claims. Questions over the validity of each part of an uncertain claim can be raised, meaning uncertain claims can be treated the same as any other claim in discourse. Translation clarifies the epistemic status of uncertain claims by distinguishing the relative certainty of each part. Mutual understanding is facilitated by the location of common basic premises between the values grounding each respondent's reaction to a potential future, even where these values lead to contradictory normative claims. The problem of uncertainty is not eliminated in the sense that the respondent's description of and reaction to the future may prove to be incorrect; however, the values grounding this reaction, which speak to how the respondent would design a desirable future (use of PHM), can be understood.

7.3.2.6 Responsibility for Translation

As is the case with transferring findings from qualitative hermeneutic research to other contexts and phenomena (Kinsella 2006), the responsibility for translation belongs to all participants in the discourse. The author of the claim, by right of participation in the discourse, needs to translate the claim into a frame of reference which resonates with other participants, which requires engaging other participants in dialogue regarding an accepted vocabulary or shared framework. Suggestions for building such a framework were given in the preceding section, although the details of the framework will vary. The need for such a framework implies that part of the responsibility for translation also belongs to other participants in the discourse.

However, beyond the desire for rational discourse and argumentation shared in principle by all participants in a discourse, the author is motivated by the desire to have his normative claim taken seriously. Responsibility for translation is placed upon the author in light of the normativity of his claim—the claim that a certain state of affairs ‘should’ occur means that the translator has a vested interest in making that state of affairs occur, through convincing other stakeholders of his perspective.

7.3.3 Translation and Credibility in Discourse

By reframing uncertain claims in terms legitimate in a specific discourse, translation opens the possibility of evaluating the credibility of uncertain claims. Translation reveals the evidence base and reasoning processes behind uncertain normative claims for further analysis in discourse, clarifying their epistemic status compared to claims about current practices or phenomena. In this sense translation serves a critical role—it exposes weak and unfounded claims which can be discarded due to a lack of credibility. As previously mentioned a shared purpose of hermeneutic dialogue and rational discourse is to facilitate cooperative life rather than discover absolute truths (see: Section 6.1.3.3); the same can be said for translation—to be successful it need only be comprehensible and acceptable to others, allowing them to understand the motivations and evidence behind a claim, which opens the possibility of revision and acceptance in discourse.

In establishing the epistemic status of uncertain normative claims, translation distinguishes between legitimate and illegitimate claims requiring evaluation in discourse. The range of claims encountered in empirical research can be narrowed to those which are potentially

credible, meaning those capable of providing justification for actions. Translation therefore helps identify claims encountered in the empirical study which should be considered in applying and refining the conceptual framework by distinguishing between the uncertain components of a claim and the moral values informing it. As the purpose of the empirical study is to identify moral values, ethical concepts and other perspectives indicating potential ethical implications of PHM, and to assess whether these components can be explained through the conceptual framework or, rather, indicate a need to refine it, the separation of uncertain claims into uncertain and certain components through translation is therefore a crucial step to how 'theory building' or refinement of the framework will occur in practice (see: Chapter 9). The purpose here is not to judge the relative credibility of any particular statement as would be required in moral decision-making for a particular case, but rather to gain a broader perspective on the range of relevant considerations which should be accounted for in a conceptual framework built to improve future discourses.

7.4 Conclusion

The empirical methodology described in the previous chapter has been expanded in this chapter with further epistemological and methodological considerations, relating to the difficulties posed by uncertainty and the possibility of combining ethical theory and empirical data in ethical analysis, respectively. The approach described in this and the previous chapter is designed to 'test' the explanatory power and identify potential refinements for a conceptual framework, which was constructed to help identify and explain ethical issues in future contexts relating to medical relationships.

In Chapter 6, hermeneutic dialogue was suggested as an appropriate method for empirical research in which the perspectives of potential users of PHM can be critically assessed. In this chapter, discourse ethics was used to create an epistemic framework to justify serious consideration of uncertain normative claims in dialogue (or discourse). The ideal of rational discourse detailed in the TCA provides a critical standard against which the legitimacy of uncertain claims can be judged through translation. According to translation, claims must be comprehensible and acceptable to the stakeholders involved in a discourse to be legitimate, while a responsibility exists for participants in a discourse to translate uncertain claims. Discourse ethics, through the need for translation of uncertain claims, provides a way to critically question and clarify the epistemic value of components of uncertain claims, separating legitimate and illegitimate components distinct from their relative credibility in the

discourse. Considered together, these elements create an epistemic framework justifying both the outcomes of the empirical study as legitimate (and initially credible) as well as their inclusion in ethical analysis. Testing and refining the conceptual framework against the fieldwork is therefore justified.

If the defence offered above is seen as credible, it follows that the construction and refinement of the conceptual framework is methodologically and epistemologically sound. To proceed with development of the framework an empirical study was carried out, in which potential users of PHM were engaged in hermeneutic dialogue (see: Section 6.1.3.3) to gather the sort of normative empirical data necessary for ethical analysis under the empirical ethics mindset. The following two chapters describe the study and its results, and how the methodology and epistemology of the preceding chapters were translated into practical research activities valuable to improving the conceptual framework.

8 Chapter 8: Description of the Study

8.1 Introduction

To help understand the applicability and limitations of the conceptual framework to the experiences of potential users of PHM, a qualitative interview-based empirical study was carried out between May 2011 and July 2013 in England looking at the ethical implications of PHM mediating relationships between NHS patients, clinicians and care commissioners.⁸⁵ Ethical assessment focused on the perspectives of stakeholders in PHM-mediated relationships by engaging potential users, data custodians and service providers in a hermeneutic dialogue. The case study examined the perspectives of potential users of PHM based at three NHS sites in the East Midlands. The study sample consisted of clinicians and care commissioners working for these sites, as well as patients accessing their care.

As explained in Chapter 6, the empirical study can be seen as an ‘exploratory case study’ in which potential implications of an emerging technology are assessed. Case studies typically assess a historical project or use of a technology (see: Section 6.2.2); the study here is exploratory in the sense that potential uses of an emerging technology are assessed, based on analysis of strategy in England describing perceived uses and benefits of the technology, and perspectives of potential stakeholders in future uses. Although the moniker ‘case study’ is not perfect, it highlights the potential for medical relationships between participants despite reigning uncertainty over future uses of PHM in any particular NHS institution.

8.2 Sample

An overwhelming focus on the ethical implications of PHM as experienced by elderly patients was revealed in the literature review (see: Section 3.3.1). The empirical study was designed to broaden the discourse by engaging with potential users of all ages, as well as carers, clinicians and care commissioners.⁸⁶ Reflecting the effort to identify unforeseen ethical implications for

⁸⁵ The study built upon a pilot study, details of which can be found in Section 8.5.1.1.

⁸⁶ The literature review identified that the ethical implications for healthy users of PHM are not well studied (see: Section 3.3.1). Although this group would have made for an interesting study sample, they were not recruited on the basis that piloting by the NHS focuses on chronic illness management, which provides the best indication of how PHM will be initially used (in medical care) in England in the near future. With this said, ‘healthy’ PHM may experience rapid uptake in the near future for uses outside of medical care provided by the NHS. This is however merely speculation: the literature review revealed few ‘healthy’ PHM applications or uses of the technology for healthy individuals (see: Appendix 1 Table 1.2), so pursuing speculation in the research project could not be justified.

medical relationships outside of the framework developed in Chapter 3, the study sample was diverse, incorporating experiences and expertise of those living with, caring or commissioning for a variety of health conditions.

8.2.1 Criteria for Participation

Criteria for participation in the study were initially broad. 'Patients' needed to be diagnosed with diabetes mellitus or hypertension, or be responsible for caring for someone with dementia. Prior experience with any type of home health monitoring, not limited to PHM or related technologies, was not a prerequisite for participation but was desirable. 'Clinicians' needed to have a consultancy role for one of the three conditions at a medical centre based in the East Midlands, show interest in the potential of PHM for providing care, and be willing to help with recruitment. 'Care commissioners' needed to fulfil a role in a local NHS trust or CCG responsible for purchasing or commissioning medical care or technologies, preferably with experience in piloting PHM through telehealth or telecare schemes.

8.2.2 Participant Groups

Participants were divided into two broad groups: 'patients' and 'professionals'. For patients, sub-groups were defined by health condition, resulting in three 'patient' sub-groups: diabetes mellitus, hypertension and dementia. For professionals, sub-groups were defined by professional role in healthcare, resulting in three 'professional' sub-groups: disease specialists, service officers and care commissioners. Different perspectives were expected for each group based upon their medical experiences.

8.2.2.1 'Patient' Groups

PHM applications and implementation are designed around the medical needs of target audiences. Realising this, the sample was designed against the target audience of emerging PHM applications, designed either for monitoring patients with specific medical conditions, or physiological parameters relevant to the management of the chosen conditions. To make the study's results relevant to foreseeable uses of PHM in England, individuals were recruited with health conditions matching those found in existing development (see: Chapter 2) and NHS piloting (see: Section 5.3.1). Chosen conditions needed to present opportunities for monitoring which contributed to (in)formal medical care. Ethically interesting characteristics of the condition which created unique opportunities for monitoring (e.g. wandering tracking for dementia), based on the review of the discourse in Chapter 3, were also considered. This

approach identified patient groups for whom future medical interactions mediated by PHM are likely to give rise to ethical issues.

Dementia, hypertension and diabetes mellitus represent a cross-section of medical conditions targeted by early uses of PHM in England. Each of these conditions offers unique experiences and medical requirements which make them desirable for empirical study. These conditions were chosen over others involved in NHS piloting, such as COPD, due to these characteristics.⁸⁷ All three conditions require longitudinal management of symptoms and are generally incurable, meaning they are a long-term burden on NHS resources, thereby fitting into the DH's strategy of telehealth and telecare support to reduce costs in long-term care (see: Section 5.2). Each condition is seen as uniquely valuable to the study on the basis of how PHM may be incorporated into longitudinal management of the condition, and the potential implications this has for medical relationships.

8.2.2.1.1 Dementia

Dementia is a group of degenerative neural symptoms affecting approximately 800,000 people in England. The condition is most common in people above the age of 65. Symptoms include an ongoing decline in brain activities, including "memory loss, thinking speed, mental agility, language, understanding, judgment," problem solving or tasks requiring concentration, as well as the capacity to make autonomous decisions (Choices 2013a). Symptoms progress at different speeds in different patients, and may be temporarily controlled or slowed with medication; most types of dementia are, however, incurable. Changes in the personality and sociability of the patient are common, including difficulty with controlling emotions, engaging in social situations, lying, apathy towards activities, and a loss of empathy or compassion towards others. Independent living can become a challenge, including making decisions and plans about the future, which often leads to the need for a live-in carer or occasional visits from family and friends to help with daily activities, such as cooking and cleaning (Choices 2013a). In some cases, a decision-making proxy is necessary when the person is believed to have lost their capacity for independent decision-making.

⁸⁷ From a pragmatic perspective, COPD initially came to the author's attention with the publication of the results of WSD in 2012-13 (cf. Steventon et al. 2012; Cartwright et al. 2013). Altering the sample at this late stage of the project would have required reapplication for NHS ethical clearance, which was not feasible in the project's timeframe (see: Section 8.4).

Dementia was chosen for the study because symptoms present unique opportunities for health monitoring, including tracking the location of the patient to prevent wandering (cf. Robinson et al. 2007), memory aides to assist with daily activities such as taking medication, or in-home sensors to detect behaviours deemed problematic or symptomatic of a developing health condition (cf. Mahoney et al. 2007). These types of features present unique ethical issues relating to the privacy and autonomy of individuals with impaired mental facilities, and appropriate levels of monitoring in the pursuit of safety. Other types of PHM applicable to a wider elderly audience are also relevant to PHM, such as smart homes and fall detectors (cf. Frisardi & Imbimbo 2011). The applicability of a wide range of PHM applications, some of which overlap with applications designed for the elderly in general, meant that including dementia carers in the study allowed for exploration of ethical issues both unique to the mentally impaired and shared with dependent elderly users.

PHM (or telecare) is seen as a method to enable dependent elderly individuals, such as those with dementia, to age-at-home independently for an extended period of time before requiring live-in care or a move to residential care (Department of Health 2011b). Dementia therefore fits the requirement of the 'Three Million Lives' campaign to support telecare usage among patients with social and home care needs (see: Section 5.3). The move towards in-home monitoring for ageing-at-home needs to consider the impact on family members before being pursued further, as an increase in care at home will increase the need for informal carers as long as face-to-face care is deemed necessary to fulfil medical or social needs (Palm 2011). In this sense, PHM implies a greater care burden for family and friends of dependent elderly individuals. Informal carers, or family and friends undertaking 'voluntary' care, often experience significant changes in their personal relationship with the patient, resulting in antipathy, role reversals and loss of social contact (Palm 2011). However, PHM may affect how relationships between carer and patient develop, perhaps alleviating some of the care burden through technological monitoring and thus relieving the effects on social roles. When live-in care is unavailable or impractical, PHM may provide a means to monitor the safety and activity of the individual with dementia in their home without the need for constant human presence. On this basis PHM may affect how relationships between patients, family and friends change with the onset of dementia; reducing dependency on human care through remote monitoring may relieve some of the burdens placed on carers, but potentially at the cost of the patient's well-being (see: Section 3.2.6). This situation provides a reason to study the implications of PHM on the relationships between dementia patients, carers and clinicians.

For reasons connected to ethical approval, it was not possible to recruit patients with dementia to the study. Instead, individuals caring for someone with dementia were recruited. To avoid confusion these carers are referred to as 'patients' when speaking of the participant groups, despite not having dementia themselves.

8.2.2.1.2 Diabetes Mellitus

Diabetes mellitus is a progressive condition affecting approximately 2.9 million people in England in which blood sugar (glucose) levels are elevated due to an imbalance of insulin in the blood or the development of insulin resistance in the body's cells. Elevated glucose levels sustained over a long period of time can damage organs, nerves and blood vessels. The most common form of diabetes mellitus is Type 2, affecting over 90% of all diagnosed individuals, in which the pancreas fails to produce sufficient insulin. Type 1 diabetes mellitus is characterised by the pancreas failing to produce any insulin, necessitating daily glucose monitoring and insulin injections to maintain acceptable levels of glucose in the blood. Type 1 diabetes mellitus typically develops during teenage years, whereas Type 2 is typically diagnosed in individuals over the age of 40, although younger people have been increasingly diagnosed in recent years. Type 2 is often associated with obesity, and is sometimes accompanied by hypertension or high blood pressure (Choices 2013b), suggesting that a crossover may exist between the patient groups recruited to the study.

Although diabetes mellitus is incurable, Type 2 can often be managed through lifestyle changes, including diet and exercise. As the condition progresses monitoring blood sugar levels may become necessary, along with the introduction of medications and insulin injections designed to bring blood sugar to normal levels. Type 1 diabetes mellitus requires these sort of interventions throughout the life of the patient (Choices 2013b), whereas not all Type 2 patients require monitoring because symptoms can be managed through lifestyle choices.

Both types of diabetes mellitus present opportunities for PHM to assist in the management of lifestyle changes and monitoring of glucose levels. Lifestyle monitors (cf. Ganti et al. 2010; Bowes et al. 2011) can help patients manage exercise routines and diet, and provide feedback on activities based on recommendations from a GP or other practitioner. Body area networks (cf. Jones et al. 2010) and in-vivo glucose monitors could provide constant monitoring of blood sugar levels (cf. PositiveID 2011), and perhaps be combined with an in-vivo insulin pump (cf.

LaVan et al. 2003) to automatically regulate insulin levels from inside the patient's body based on real-time data.

In terms of inclusion in the study, diabetes mellitus was chosen in part because of piloting in the WSD targeting the condition (see: Section 5.3.1), which suggests PHM may be used in diabetes management in the near future. Beyond pragmatic reasons, the implications of lifelong monitoring and management of symptoms on PHM mediated relationships remains unclear. Prior monitoring of glucose levels may affect attitudes towards longitudinal monitoring offered by emerging PHM. For example, a patient accustomed to monitoring glucose levels daily may be less critical of PHM because monitoring is already part of his daily routine. It may also be more difficult for those accustomed to daily glucose monitoring to grasp the differences between PHM and existing arrangements in terms of the type of data gathered and the implications of sharing it with the NHS. For individuals without such a routine, longitudinal collection and transmission of personal health data may be considered a form of medicalisation, with the monitor viewed as a reminder of a health condition or as a symbol of practitioner expectations of healthy behaviour (cf. Kaplan & Litewka 2008). The feedback loop inherent to lifestyle monitors, by which lifestyle recommendations can be made on the basis of real-time data, raises questions regarding autonomy and coercion of patients to adhere to treatment recommendations. Such coercion may be self-imposed through expectations of self-care or self-monitoring accompanying power shifts towards shared decision-making, as is implicit in the Department of Health's information strategy (Department of Health 2012a), or explicit through clinicians referring to PHM data as an 'objective' record of the patients behaviour. All of these implications suggest changing locations of power and responsibility for care in relationships between patient, clinician and the NHS.

8.2.2.1.3 Hypertension

Hypertension is the clinical name for high blood pressure, a condition in which the pressure or force with which blood presses on the walls of the arteries when being pumped around the body is consistently above a 'normal' range. To qualify as elevated, multiple blood pressure readings must register above 140/90mmHg (millimetres of mercury) over an extended period of time. Hypertension does not have any obvious symptoms, but increases the likelihood of other complications including cardiovascular diseases, heart attack, stroke, kidney disease and complications stemming from diabetes mellitus. Individuals with diabetes mellitus will often develop high blood pressure at some point in their life, leading to other medical complications.

Unlike dementia and diabetes mellitus, hypertension can be 'cured' by returning blood pressure to a 'normal' range, although individuals with high blood pressure will typically require monitoring and management throughout their life to ensure readings stay within the acceptable range. Treatments are often based on lifestyle changes including weight loss, exercise, diet, and reductions in smoking and consumption of alcohol. Medication may also be used to lower blood pressure, particularly among patients for whom lifestyle changes are ineffective. Hypertension affects around 30% of the English population and can be diagnosed in individuals of all ages, but the risk of developing hypertension is seen to increase with age, particularly above the age of 65 (Choices 2013c).

Despite the ability to 'cure' hypertension, most patients experience it as a long-term condition requiring lifelong management (Ramsay et al. 1999). Monitoring occurs through regular blood pressure checks, often carried out at regular visits to the GP, although some patients monitor on a regular (sometimes daily) basis at home (Choices 2013c). Different types of monitors can provide different types of readings regarded as more or less accurate representations of the patient's 'true' blood pressure (White et al. 1990). Blood pressure fluctuates naturally throughout the day, which suggests that readings taken at regular, short intervals are increasingly accurate representations of the patient's true blood pressure. Recognising this, manual readings are often taken twice in quick succession following a period of rest to find a 'true' reading (Ramsay et al. 1999). Longer term monitoring is occasionally necessary to find a true reading, often over a period of 24 hours (Stergiou & Bliziotis 2011), during which the patient wears a device which automatically takes readings at set intervals (e.g. every 30 minutes for 24 hours).

Based on existing medical practice, a need exists for regular monitoring of blood pressure in hypertensive patients. Frequent monitoring is believed to provide a truer representation of a patient's blood pressure over time; despite this, such monitoring is typically limited to infrequent instances of 24-hour monitoring with automated blood pressure cuffs (Stergiou & Bliziotis 2011). PHM applications applicable to hypertension include wrist watch style devices (cf. Laurance 2011) and body area networks consisting of multiple wireless sensors monitoring various physiological parameters including blood pressure (Milenkovic et al. 2006; Jones et al. 2010; Pantelopoulos & Bourbakis 2010). As with diabetes mellitus, individuals with hypertension may also find lifestyle monitors useful in managing their condition through lifestyle changes.

In terms of inclusion in the study, hypertension was chosen in part because of DH piloting of blood pressure monitors in the WSD (see: Section 5.3.1). Positive results connected to blood pressure monitors in the WSD (Steventon et al. 2012) suggest that the technology will continue to be supported and perhaps piloted in other contexts, such as hypertension management (Department of Health 2011a). With this said, a primary aim of the WSD was to measure the effect of telehealth on the reduction of emergency hospital admissions in monitored patients (Steventon et al. 2012), so it remains unclear whether this outcome would motivate deployment of monitors to hypertension patients. From a clinical perspective 24-hour monitoring data is seen as a more accurate representation of the patient's blood pressure over time compared to one-off readings (Stergiou & Bliziotis 2011), so PHM applications providing such data have at least one clear benefit to patients and may gain clinical support as a result.

Beyond NHS and clinical support, hypertension was chosen because self-management of the condition, often through blood pressure monitoring and lifestyle, is already common. It stands to reason that PHM applications which provide feedback on the impact of lifestyle choices on blood pressure over time would be attractive to patients attempting to self-manage their condition; whether such self-reliance is safe or part of a desirable change to the doctor-patient relationship is an open question.

8.2.2.1.3.1 Links between Hypertension and Diabetes Mellitus

Hypertension was chosen based on its similarity to diabetes mellitus, in the sense that both types of patients may have prior experience with monitoring. With this said, the two groups are different in terms of the importance of recognising abnormal readings and intervening quickly, which may affect attitudes towards longitudinal or constant monitoring. Glucose levels fluctuate and are categorised as normal or problematic by individual readings at any given time; one-off readings can indicate a serious health risk, such as a hypoglycaemia attack (Choices 2013b). Both high and low blood glucose levels can cause tissue damage and other complications in a relatively short period of time (e.g. hours) (Ferry 2013). Abnormal levels can be treated immediately through insulin injections or medication, suggesting that constant readings combined with appropriate interventions (e.g. insulin injections) could reduce the complications experienced from high or low blood sugar. For blood pressure, the same is not true; a single elevated blood pressure reading does not indicate hypertension (Choices 2013c), and thus does not create a need for immediate corrective action. However, longitudinal readings at short-term intervals may provide a more accurate picture of blood pressure over

time (cf. Stergiou & Bliziotis 2011). As a result, diabetes mellitus and hypertension patients may have different attitudes towards monitoring based on the different uses of monitoring data regarding condition management.

8.2.2.2 'Professional' Groups

Medical professionals were recruited to the study to provide perspectives from the 'other end' of the healing relationship. In other words, professionals provided information about the perceived uses of PHM from a clinical and commissioning perspective, which helped clarify how PHM may be used in the future care of individuals with dementia, diabetes mellitus or hypertension. Three types of professionals were recruited, each with unique insight into how PHM can change relationships between themselves, patients, and the NHS based on their existing role in medical care.

8.2.2.2.1 Disease Specialists

Disease specialists are clinicians, typically a GP, consulting physician or specialist nurse, responsible for working with patients to manage a chronic illness through face-to-face clinical encounters, treatment and lifestyle recommendations. For the study, specialists can speak to how PHM applications may be used in treating chronic patients, including concerns or benefits with PHM mediating the patient's care which may limit face-to-face encounters. Specialists also have insight into using PHM data in managing a patient's condition, perhaps by providing feedback directly to the patient without clinical intervention.

Beyond clinical care, specialists can also speak to interactions with medical institutions, and the influence of institutional strategy and policies on clinical care. Given the potential for PHM to move the location of care out of surgeries and hospitals, clinicians are uniquely positioned to speak to the ethical desirability of increasingly putting patients on treatment regimes involving monitoring and self-management.

8.2.2.2.2 Service Officers

For reasons explained below (see: Section 8.4), recruitment of a disease specialist for dementia was not possible. A suitable replacement was found in non-NHS professionals responsible for organising community support services, which support informal dementia carers by organising support groups, listening to carer concerns and disseminating information about care services. The organisers of these services, with expertise in the needs of dementia carers and the availability of professional care and support services, are referred to here as 'service officers'.

For the study, service officers provide insight into the needs and experiences of dementia carers, as well as shortfalls in existing NHS and social care services to meet these needs. As organisers of support services these individuals have insight into problems faced by dementia carers, such as those of time management and emotional stress from the change in character of a loved one as dementia progresses. Information carers are responsible for a majority of dementia care in England, so the insight of professionals with knowledge of their concerns is valuable in understanding how PHM may change the relationship between patients and family members providing care. Service officers also occupy a unique place between informal carers and the NHS from which they can identify shortfalls in professional care services potentially met by monitoring, and the implications for human interaction in care of installing a monitor.

8.2.2.2.3 Care Commissioners

Care commissioners recruited to the study to provide insight into the attitude of NHS organisations towards PHM, or the context in which patient attitudes can be assessed. Specifically, care commissioners help explain local strategy supporting diffusion of PHM, or how the technology and its data may come to be used in the near future in the care of patient participants. Commissioners are uniquely placed to provide transparency regarding the decision processes which lead to PHM being offered to patients in clinical care, processes which have historically been difficult to understand from outside the NHS (Jones et al. 1995; Wade et al. 2006). Recognising that diffusion is a complex and contested process, not following a linear path (see: Section 5.3), commissioners can also discuss the influence of DH strategy and NICE guidelines on local commissioning. Beyond this, the reasoning behind commissioning decisions reveals aspects of PHM seen as valuable at an organisational level, for example the reduction of hospital admissions (cf. Ure et al. 2012). Commissioners may also have experience with the barriers and benefits faced in piloting PHM, or related technologies such as telehealth. Finally, commissioners have insight into the role PHM data may play in future commissioning decisions, and the extent to which data will be strategically used to encourage self-management among patients.

8.2.3 Summary

The sample consists of 23 people, including fifteen patients and eight professionals. Fifteen participants are women and eight men, aged between 36 and 82 years old, with a median age of 62. Of the fifteen 'patients', five have diabetes, five have hypertension, and five care for someone with dementia. Of the eight professionals, three are care commissioners and three

are disease specialists with NHS organisations from the same region, while two are service officers at a dementia charity. Of the disease specialists, one is a consulting specialist in hypertension, one is as a consulting specialist in diabetes mellitus, and one is a diabetes specialist nurse.

Of the patient sample, two individuals with diabetes and one dementia carer have prior experience with using health monitoring (glucose monitoring and fall detectors, respectively). All five patients with hypertension currently monitor their blood pressure at home, or have done so for extended periods of time in the past (see: Table 8.1).

Identifier	Group	Health Monitoring at Home
DP1	Diabetes Mellitus	None
DP2	Diabetes Mellitus	Manual glucose monitor and insulin pump
DP3	Diabetes Mellitus	Manual glucose monitor (not current)
DP4	Diabetes Mellitus	None
DP5	Diabetes Mellitus	None
HP1	Hypertension	Blood pressure cuff with log, pulse monitor
HP2	Hypertension	Blood pressure cuff with log (not current), 24-hour monitor (one time use)
HP3	Hypertension	Blood pressure cuff with log, exercise monitor wrist watch and belt
HP4	Hypertension	Blood pressure cuff with log
HP5	Hypertension	Blood pressure cuff, 24-hour monitor (one time use)
DC1	Dementia Care	None
DC2	Dementia Care	None
DC3	Dementia Care	Automatic medication dispenser
DC4	Dementia Care	None
DC5	Dementia Care	None

Table 8.1 - Patient Participants

All disease specialists, service officers and care commissioners are familiar with PHM and are currently involved with health monitoring to some degree (see: Table 8.2). One care commissioner is currently working with a related technology as manager of a telehealth programme for COPD patients.

Identifier	Group	Health Monitoring in Professional Role
DS1	Disease Specialist – Diabetes Mellitus	Short-term ‘always on’ glucose sensors for patients with erratic glucose levels. Limited uses. Food/exercise/insulin diary.
DS2	Disease Specialist – Diabetes Mellitus	Analyses manual blood pressure (BP) and glucose monitoring data provided by patients. Food/exercise/insulin diary.
HS1	Disease Specialist – Hypertension	One-off 24-hour home blood pressure monitor for difficult cases of hypertension.
DM1	Service Officer – Dementia	Recommends assistive technologies for dementia patients including door sensors, smart pillboxes and fall detectors.
DM2	Service Officer – Dementia	Recommends assistive technologies for dementia patients including door sensors, smart pillboxes and fall detectors.
CC1	Care Commissioner	Involved in strategic planning for telehealth, telecare and other care services.
CC2	Care Commissioner	Manages a small-scale telehealth programme for the local CCG.
CC3	Care Commissioner	Designed a telehealth programme for a local NHS trust. Involved in planning of telehealth initiatives at the trust.

Table 8.2 - Professional Participants

As mentioned above (see: Section 6.2.2), the study can be conceived of as an ‘exploratory case study’. A further qualification to this concept is necessary because the study did not look at a single case based on the recruited sample; rather, it included three broad groups of participants, with patients sub-divided into three disease groups. It therefore cannot claim the sort of in-depth examination of a single case or systematic examination of multiple data sources (e.g. observations) typically associated with the case study method. This decision should not be seen as a weakness; it was decided to include multiple participant groups because all participants were *potential* as opposed to *actual* users of PHM. If a single case had been chosen, the study would have risked studying a phenomenon that never occurred. Furthermore, in the place of multiple data sources, participants were recruited to provide patient, clinical and institutional perspectives, all of which were considered within the context of strategic support and proposed uses of PHM in England. The study therefore still provided

in-depth analysis of a particular context, albeit without the uses of multiple data sources gathered during the study itself.

8.3 Location

The case study involved patients and professionals from the East Midlands. The context of the study is two NHS trusts and one CCG covering a region in the East Midlands. Disease specialists and care commissioners were recruited from these NHS organisations, which are currently implementing a telehealth programme for chronic illness management. Similar to the WSD, the programme provides 'question-and-answer' telehealth systems to COPD patients aimed at reducing the length and frequency of hospital admissions. Elsewhere in the region, local councils provide assistive technologies for elderly individuals with social care needs, including fall detectors, motion and weight sensors, and emergency alert systems. However, these systems lack longitudinal monitoring capabilities, being limited to one-off alerts to carers.

As the sample needed only to consist of potential users of PHM with diabetes mellitus, hypertension or experience with dementia care, no appreciable differences are evident between the East Midlands and other regions of England. Choice of location would have assumed greater importance had existing users of telehealth and telecare systems related to PHM been sought from existing pilot programmes (e.g. Department of Health 2011a; Ure et al. 2012) (see: Section 10.5).

8.4 Recruitment and Research Ethics Approval

Recruiting the sample started with the identification of diabetes mellitus, hypertension and dementia specialists at local NHS hospitals, who were sent invitation letters with details of the study and a request for assistance with recruitment (see: Appendix A14.18 and A14.19). After initial enquiries, specialists in dementia, hypertension and diabetes mellitus were found through inter-organisational recommendations. Verbal agreements to assist in recruitment of patients were obtained, contingent upon research ethics approval from De Montfort University (DMU) and the NHS. According to DMU regulations, any research involving human participants requires Human Research Ethics approval to assess the potential risks of participation. The study initially obtained Human Research Ethics (HRE) approval from DMU in May 2011 (application no. 1011/014). It was made clear in the application that the NHS would be approached to assist with recruitment. As a result, DMU HRE clearance was contingent upon approval from the NHS National Research Ethics Service (NRES).

An application for NRES approval was submitted to the Leicester NRES research ethics committee (REC) in September 2011 (application no. 11/EM/0352) following six months of preparation of the application and supporting documents (e.g. consent forms, information sheets, invitation letters; see: Appendix 14). The application was rejected in October 2011, on the basis that the 'disease groups' identified in the sample were too broad to allow for the committee to give an informed decision. Including dementia patients in the study was viewed as the primary issue due to a potential lack of capacity to consent, which would have required the involvement of a practitioner in the study to assess capacity on a patient-by-patient basis. The committee recommended that the research team (e.g. the researcher and the supervisory team) attempt to recruit patients from local patient support groups, which would eliminate the need for NRES approval. When queried about the need for NRES approval to speak with NHS practitioners and care commissioners, the REC indicated that NRES approval was unnecessary.

The research team was sceptical that support groups would provide sufficiently diverse participants, meaning a sample recruited entirely from support groups would be biased towards patients fitting a certain profile (cf. Taylor et al. 1986). As a result, a second NRES application was prepared while searching for appropriate patient support groups. Receptive diabetes mellitus and hypertension groups were quickly identified in the East Midlands, while a dementia support group proved more difficult to find. After reviewing the REC's reasons for rejecting the application and discovering that local dementia charities also required NRES approval, the research team decided to switch from recruiting dementia patients to dementia carers, who present fewer ethical barriers to research found with dementia patients lacking the capacity to consent (cf. Berghmans & Ter Meulen 1995). Reflecting this, the study was re-approved by DMU in March 2012 without contingencies (application no. 1112/082) following the shift in recruitment.

The decision to recruit carers was also made based on conversations with the dementia disease specialist, who indicated that recruitment of 'early-stage' dementia patients with the capacity to consent to participation would be difficult through NHS channels because dementia is typically only diagnosed in mid to late stages, when cognitive decline becomes increasingly apparent. Additionally, as a consulting specialist her patient pool consisted of 'special' or 'problematic' cases, meaning the majority of her patients (and thus the potential

sample) have severe dementia and would therefore be ineligible for the study due to a lack of capacity to consent.

Following the change, support groups for informal dementia carers were identified, as opposed to those supporting patients. Agreement to assist in recruitment was quickly obtained from an interested dementia carer charity. Once the decision was made to focus on carers, the inclusion of a disease specialist in dementia was re-evaluated due to her expertise being in medical treatment of dementia, not dementia live-in care. On this basis she voluntarily ended her participation in the study. Two service officers working for a local dementia charity providing support services were recruited in her place, each with expertise in dementia care services and needs gained through regular contact with medical and social service organisations regarding the services offered to carers.

The first round of patient recruitment took place at support group meetings for each disorder between October 2011 and April 2012, during which invitation packets containing an invitation letter and information sheet (see: Appendix 14) were distributed following a brief presentation on PHM and the aims and structure of the study. Participants were directed on the invitation to contact the researcher if interested in the study, avoiding the need to access identifiable information to identify potential participants. Presenting the study to potential participants prior to recruitment helped limit the sample to participants interested in PHM, which may contribute to a higher quality dialogue during interviews, hopefully eliminating participants that have no opinion or interest in the technology which would lead to meaningless results. It is, however, recognised that volunteers may also have been motivated by other interests, such as a desire to help with research perceived to be socially valuable. In total twenty-three volunteers were identified via support groups, eleven of which eventually participated in the study. This stage of recruitment occurred at support groups for all three disorders, although the ethics review process was only relevant for diabetes mellitus and hypertension.

While support group recruitment was occurring, the diabetes mellitus disease specialist confirmed the research team's concerns of sample bias based on his experience with local support groups. Specifically, he suggested that the sample would be limited to patients with an interest in managing their condition and the initiative to attend monthly group meetings. These concerns were added to the revised application for NHS ethics approval, which was submitted shortly after support group recruitment concluded.

A revised NRES application was submitted to the Nottingham REC in January 2012 (application no. 12/EM/0064) in response to the changes suggested by the Leicester REC. The change of RECs was based solely on the Leicester REC not having an available slot to review the application in the next monthly meeting, while the Nottingham REC had a slot available. This seemingly minor change proved to add difficulties to the study, as the criteria for review were not standardised between the REC as would be expected of a national service. The application was rejected by Nottingham soon after being received. The REC was confused by the structure of the study, in part because of the changes requested by the Leicester REC. Additional supporting documents were also requested which had not been requested by the Leicester REC. Importantly, the Nottingham REC informed the research team that information sheets and invitation letters for medical staff would be necessary if they were being interviewed in the study. This position suggested to us that REC approval would be necessary to recruit and interview consulting specialists and care commissioners as planned. In itself this may not be surprising; however, the Nottingham REC's advice directly contradicted the advice given to the research team by the Leicester REC, who informed us during review of application 11/EM/0352 that REC approval was not necessary to interview NHS staff.

Following rejection of 12/EM/0064, another revised application was submitted to the Leicester REC in March 2012 (application no. 12/EM/0160) with the additional supporting documents requested by the Nottingham REC. The research team attended the meeting at which the application was reviewed. During the meeting, the Leicester REC again confirmed that REC approval was not necessary to interview NHS staff, contradicting the advice given by Nottingham. Following minor amendments requested by the Leicester REC, application 12/EM/0160 was approved in May 2012 (see: Appendix 19).

The next step in the NRES process was Research and Development (R&D) approval from each NHS site from which participants would be recruited. From June to October 2012 R&D approval was sought from three NHS trusts based around the East Midlands. During this time, various forms, applications and training programmes needed to be completed, including obtaining a Research Passport, a Good Clinical Practice Certificate, and training on taking consent. Finally, in late October 2012, the NRES approval process was completed and recruitment could commence via the chosen NHS sites.⁸⁸

⁸⁸ The NRES approval letter can be found in Appendix 19.

Recruitment of care commissioners and patients via NHS channels could only commence after REC and R&D approval of the study. Care commissioners were recruited by contacting local trusts and CCGs with a request to interview someone responsible for commissioning or purchasing care services or technologies, and preferably involved with telehealth or telecare piloting. This method led to the identification of ten suitable individuals through recommendations by colleagues within each trust, three of whom agreed to participate.

The second round of patient recruitment occurred between October 2012 and February 2013. Consulting clinicians were instructed to distribute invitations to participants matching an 'ideal participant profile' created by the researcher, based upon gaps in the sample identified after the first round of recruitment (see: Section 6.2.3). The profile described characteristics or experiences of an 'ideal' participant which were not well represented. Different profiles were created for diabetes mellitus and hypertension based upon the background and perspectives of first round participants from these groups. In this way purposive sampling was used to identify participants with general attitudes towards medical ICT (e.g. 'concerned', 'dismissive', 'confused', 'responsive', 'motivated') missing from the first round, as assessed by the consulting clinician responsible for their care. A profile was not used for dementia carers because a channel for recruitment beyond support groups was not available. This did not weaken the sample, however, as the attitudes of the recruited carers were found to be diverse in terms of relative support or scepticism towards the utility and benefits of the technology (see: Section 9.3.4).

The profile was intended to change as the study progressed and participants with certain characteristics were required for purposive sampling. However, as a result of the lengthy NRES approval process, the profile was not revised. Based on assessment of participants recruited via support groups, the specialists were directed to identify patients who were frustrated by the results of their attempts to manage their condition, and who had an interest in or were wary of medical technologies. With this profile four additional patient participants were recruited, two with diabetes mellitus and two with hypertension. The profile was not updated and further patients were not recruited due to the timeframe of the study, which needed to be completed by October 2013. The last patient was recruited in June 2013. Ideally, further patients matching a revised profile could have been recruited following analysis of interviews with patients recruited during the second round.

8.4.1 Criticism of NRES

Recruitment and the makeup of the sample were greatly hindered by the NHS research ethics review process. Preparation of the application for approval started in the first year of the project and was allocated 18 months in the project plan based on the supervisory team's prior experience with NRES. Even this lengthy period proved to be insufficient given the difficulties faced in the approval process, which was seen as inherently flawed, unnecessarily complex and internally inconsistent, views shared by others in England's medical research community (cf. Kerrison & Pollock 2005; Masterton & Shah 2007; Elliott & Hunter 2008; Fistein & Quilligan 2011).

Inconsistencies are apparent between the approval requirements of regional RECs, as seen in the contradictory advice given by the Leicester and Nottingham RECs which resulted in a delay of several months. Even after REC approval is granted, each research site requires separate R&D approval, which involves submitting non-standardised applications to each site which are judged against different and occasionally contradictory requirements, for example when different supporting documentation is requested by each R&D department. For academics outside the NHS, deciphering the requirements for each REC and R&D department is extremely difficult due to the poor quality of official guidance available via public channels. The guidance available on the main NRES portal (IRAS, <http://www.myresearchproject.org.uk>) fails to establish clear guidelines on participant groups (e.g. NHS professionals, clinicians) requiring approval, the expectations of the RECs regarding supporting documentation, and how to proceed with R&D applications following REC approval. This confusion may be shared by committee members, as shown in the conflicting advice given by RECs within the same NRES region.

In a system which claims to be unified and hierarchical, with common requirements for approval and standards of practice passed down from above, the extensive inconsistencies and duplication of work experienced in the process indicate a lack of hierarchical control, in effect erecting a major barrier to medical research in England (cf. Masterton & Shah 2007; Fistein & Quilligan 2011). Whether this bureaucratic barrier is intentional is unclear, although the experiences of the research team suggest it was not erected by chance. In general the RECs were overly defensive and quick to absolve themselves of responsibility to approve a study with any chance of harming patients, no matter how remote, as seen in the advice given by the Leicester REC to pursue recruitment via patient support groups to eliminate the need for REC

approval. This assertion is supported by the supervisory team's prior experiences with NRES, in which similar defensiveness was experienced. Regardless of the motivations for the bureaucracy, NRES proved to be a major hurdle to overcome in completing the research project⁸⁹, and severely limited the time that could be dedicated to data collection and analysis, particularly for interviews with NHS disease specialists and care commissioners.

8.4.2 Consequences for the Sample

NRES limited purposive sampling, which given more time would have allowed for recruitment of younger patients not well represented in the discourse (see: Section 3.3.1), particularly those with Type 1 diabetes mellitus which tends to be diagnosed as a younger age than the other disorders (Choices 2013b).⁹⁰ The sample was not intentionally biased towards older users; rather, the attendees at support groups and the patients identified by specialists were all incidentally from an older demographic.

Despite the lack of younger participants, there is no *a priori* reason why this limitation of the sample would weaken or bias the results. Attitudes towards medical technologies, including telehealth and telecare, can be linked to age (cf. Gaul & Ziefle 2009; Steele et al. 2009), although a causal relationship between age and technical literacy, or interest in medical technologies relevant to one's care, is not immediately evident. It could still be argued that the study is biased towards older chronically ill patients, weakening its generalisability. Within a hermeneutic perspective the experiences of chronic illness management which inform the perspectives of the sample are not a source of bias, but rather the framework through which they interpret the world. It would therefore be inappropriate to generalise the study's results to patients lacking similar experiences or backgrounds which define the context in which meaning is created (see: Section 6.1.3.1). In this sense, limitations imposed by NRES did not weaken the generalisability of the study. Rather, the demographic limitations may strengthen the immediate credibility of the study to England, as the primary demographic targeted in piloting telehealth and telecare devices in England match the demographic sampled (see: Section 5.3.1).

⁸⁹ The experiences of the research team may have been different had the study been initially approved via 'proportionate review'. The implications of this process for approving qualitative studies with little chance of harming patients, which emerged while the application was under review, are reviewed in Appendix 12.

⁹⁰ In the pool of patients available to the diabetes mellitus specialist who dealt with difficult cases and complications of diabetes mellitus, young Type 1 patients were rare. Although the specialist distributed invitations to a few younger patients, none subsequently contacted the author.

8.5 Data Collection

A total of 33 semi-structured interviews were completed. Participants were provided with information and consent sheets at least 48 hours prior to the interview (see: Appendix 14). Interviews lasted anywhere from 25 to 75 minutes, with most interviews running around 45 to 50 minutes. Each patient participant was intended to complete two interviews, with the first focusing on introduction of the technology, the patient's background, and initial reactions, with the second pursuing ethical implications for relationships in more detail. Professional participants were only expected to complete one interview on the basis that each had prior knowledge of telehealth and telecare, and therefore did not require a first interview to introduce the technology. Each professional was sent an executive summary of PHM and the aims of the study prior to the first interview (see: Appendix A14.22) to ensure the definition of PHM used here was understood and applied in the interviews so as to avoid limiting the discussion to telehealth and telecare. Additionally, interviews with professionals were typically longer (45-75 minutes), meaning the combined interview length between patients and professionals was comparable.

Of the patient participants, four dementia carers, three diabetes mellitus patients and three hypertension patients completed two interviews, while the remaining five patients completed one. These five only completed one interview for a variety of reasons—two patients were repeatedly contacted for a second interview but failed to respond, two patients were recruited via the NHS in June 2013 and did not have time to complete a second interview, and one patient withdrew from the study following the request for a second interview due to a death in the family. The two patients which failed to respond for a second interview showed a lack of interest in the technology and could not see any personal use for it, which may explain their reluctance to participate further in the study.

The study was designed around two interviews occurring 4-6 weeks apart to allow for a period of reflection between the interviews, based on the assumption that participants would be unfamiliar with PHM and therefore find it difficult to identify ethical implications or construct reasoned responses to scenarios posed by the interviewer in the first session. In practice, this assumption did not hold; patients were able to identify problems with the technology during the first interview and answer the researcher's follow-up questions.⁹¹ A second interview with

⁹¹ A possible explanation for this finding is that most patients first learned of PHM during presentation of the study at patient support groups (see: Section 8.4), instead of the first interview.

all participants would have been ideal to allow participants to change their minds or self-assess the basis of their reactions to PHM, potentially identifying a greater quantity of ethical implications of PHM as a mediator in medical relationships. However, each claim made by the participant was independently justified throughout both interviews, meaning the interviews can be divided into separate claims with supporting evidence, reasoning and values. In this sense the quality of the discourse was not degraded, but rather the quantity of claims encountered was reduced. Additionally, claims justified by participants were only one way in which perspectives relevant to the conceptual framework were identified; occasionally an unjustified claim or statement unrelated to ethical aspects of PHM would ‘trigger’ the researcher to identify an unforeseen issue, concept or specification. In both cases the credibility of claims encountered in the study and their relevance to the conceptual framework in terms of explanatory power and expansion were not derived from participation in a second interview.

8.5.1 Structure of the Interviews

Interviews were loosely structured around an interview guide designed to keep the discussion on-topic while allowing for participant leadership in terms of topics discussed (see: Section 6.2.4). The guide was built initially upon the findings of the literature review (see: Chapter 2) and the conceptual framework (see: Chapter 4), and iteratively updated with findings from prior interviews (Patterson & Williams 2002, pp.43–4).⁹² The guide was not a rigid list of topics to discuss, but rather general themes to pursue depending upon the interests and background of the participant. Although the interviews were guided by an interview guide as well as topics and claims raised by the participant as opposed to a pre-defined list of questions, in practice they followed a general pattern within each participant group. For patients, the first interview started with questions about (1) the participant’s personal background, (2) medical history and (3) prior experience with monitoring, followed by the researcher describing (4) PHM applications that might be relevant to their medical or care needs. Mock-ups of PHM data were shown to participants when describing applications relevant to their personal background (see: Appendix 15). The mock-ups served as a starting point for the rest of the interview as (5) a dialogue about ethical implications of the described applications, in which the participant described what they found appealing and problematic about the application. The researcher would then ask follow-up questions to understand the values that informed the

⁹² The first iteration of the interview guide can be seen in Appendix A14.23.

participant's judgment of right and wrong, and to discover the specific implications or technical capacities of the system that they found troubling. To help analyse the data within the conceptual framework developed in Chapter 3, follow-up questions often focused on the patient's reaction in terms of the impact of the technology on their home, relationships with family and friends, implications of sharing data with third parties, or how their GP or disease specialist would react to the patient using the technology. In this way medical relationships served as a thematic focal point in questioning.

The PHM applications and mock-ups described during step 4 were posed as scenarios in which monitoring was installed into the user's life to varying degrees, and with a variety of purposes. These scenarios were created around the specific background and medical needs of the participant. Increasingly pervasive or ethically questionable forms of monitoring and uses of data were posed in an attempt to incite moral judgments in reaction to the scenarios described. The scenarios used to elicit moral judgments were based on monitoring systems and goals of monitoring found in the reviewed literature (see: Chapter 3), and when possible were imagined as part of NHS piloting or strategy (see: Chapter 5). As the interview proceeded the scenarios were modified to explore the particular values on which judgments were based, or to modify a particular technological characteristic, usage of the gathered data, or goal of monitoring to which the participant objected.

As an example, a patient requiring blood pressure monitoring to control his hypertension was first offered a 24-hour blood pressure wrist watch, seen as 'unobtrusive' by most participants. The need for behavioural data to better understand the background influences on the patients BP was then explained, followed by a variety of behaviour monitoring systems, from a basic accelerometer/pedometer to an in-home motion and pressure sensing system and finally, an in-home system with video cameras. By offering increasingly provocative scenarios the values and reasoning by which participants made moral judgments was increasingly understood and questioned. A 'line' past which monitoring was no longer ethically acceptable was frequently discovered (often in connection to cameras), followed by exploration of the distinction between acceptable and unacceptable monitoring.

Where a second interview occurred, the researcher briefly reviewed topics and the participant's claims from the first interview. Follow-up questions were similar to those in the first interview, but also addressed whether the participant's claim or attitude had changed

over time, as well as the background reasoning or evidence which supported the participant's ethical judgments. The latter step was crucial because the participant's claims were hypothetical, based upon descriptions of emerging technologies with which they did not have hands-on experience. To improve the translation of such uncertain claims, the underlying reasoning and evidence needed to be understood.

Interviews with professional participants followed the same basic structure, although steps 1 and 2 were replaced with questions about the participant's professional background and professional responsibilities in providing medical care, support to patients or commissioning. Step 4 was adapted to the needs of professional's patients. Telehealth and telecare systems previously used by the participants were also used as examples in the dialogue, with hypothetical modifications to meet the definition of PHM when necessary, such as the replacement of a manual blood pressure cuff hooked to a telehealth system with a body area network with blood pressure sensors.

Topics, concepts and perspectives from earlier interviews were discussed in subsequent interviews when relevant to the ongoing dialogue. Open-ended questions, non-verbal cues and summaries were used to encourage participants to lead the dialogue in terms of topics discussed (Britten 1995; Patterson & Williams 2002, pp.44–5; Gilbert 2008), while probes forced participants to further explain the beliefs and moral values underlying their answers, uncovering issues and perspectives unforeseen by the researcher as relevant to the conceptual framework.

8.5.1.1 *Piloting*

The interview and analysis methodology built upon the results of a pilot study conducted between June and July 2011. Eight interviews were conducted with Health & Life Sciences faculty members at DMU to help develop the researcher's interviewing abilities, refine the study methodology and narrow the scope of the research project. Members of the faculty were recruited on the basis of their prior professional experiences in medicine, which facilitated understanding the technological capacities and (hopefully) ethical implications of PHM, even though none of the pilot participants had prior experience with the technology. As former clinicians or medical support staff, the participants were able to speak from both a professional and patient perspective. The pilot sample was distinct from the main study sample in the sense that participants lacked experience with chronic illness management as

well as expertise in the chosen diseases. This difference was logically unavoidable—piloting helped identify the need to recruit individuals (responsible for the care of individuals) with chronic illnesses. As the piloting data is not analysed in combination with the main study (see: Chapter 9), the mismatch between samples does not have any appreciable implications for the outcome of the research.

The pilot interviews were not fundamentally methodologically different from the interviews in the main study, although at the time the methodology was based on Denzin's interpretive interactionism (2001). Piloting revealed that interpretive interactionism was inappropriate for interviews in which an 'epiphany', or transformative moment of sudden realisation and change which changes a person's life or their view on a subject forever (Denzin 2001), is not the phenomenon under study. Attitudes towards future use of PHM do not inherently contain an epiphany moment. A shift to hermeneutics as philosophical paradigm occurred after piloting. The paradigm shift did not create a need to radically redesign the study or interviews, as hermeneutics and interpretive interactionism are seen as inherently compatible (Wilford 2004).

During the first round of pilot interviews participants struggled to understand the researcher's verbal description of PHM. In response, scenarios of use (see: Section 8.5.1) were adapted to the personal, medical or professional background of the participant during the second round of interviews, which improved the participants' grasp of PHM applications.⁹³

8.5.1.2 PHM Charts

Despite the improvements gained from personalised scenarios, participants still struggled to understand the implications of PHM data in terms of the information it could reveal about them to others, for example through combination with other data already held by the NHS. On this basis, mock-ups charts of PHM data were created showing various health and behavioural parameters tracked over time and in combination with other types of data (see: Appendix 15). The charts were validated by Mark Shaw, a medical doctor on the supervisory team.

⁹³ This improvement influenced the decision to make a brief presentation about PHM to potential participants prior to distributing invitation packets (see: Section 8.4). The presentation included pictures and descriptions of PHM applications relevant to each patient group.

A total of eight charts were used in the study. Four charts were created by the researcher, two of which showed blood pressure and glucose readings over time combined with activity logs. Two other charts shown together to participants represented pedometer readings and weight measured over a year (see: Appendix A15.1 to A15.4). An additional four charts were taken from a prior study (Beaudin et al. 2006a) into the perceived benefits and concerns attached to longitudinal health monitoring at home with ubiquitous computing systems (see: Appendix A15.5). The borrowed charts showed how connections can be made between behavioural and physiological data, as well as differences between traditional clinical or one-off monitoring and longitudinal monitoring. The study recognised that participants struggle with discussing and relating certain “home health tracking concepts” (Beaudin et al. 2006a) to their personal background:

- “ 1. Data collected over time can reveal patterns of change.
2. Context can be used to interpret reasons for change.
3. Comparisons can be made with population norms, personal goals/estimates, and peers’ values.
4. Quantitative data can be used in combination with qualitative data (eg, journal entries).
5. Multiple metrics can be applied to assess health and behaviour change.
6. Data can be used to motivate by highlighting the extent of a problem or documenting progress.
7. Data can be used to problem solve and evaluate interventions.
8. Data can be subjectively reported or objectively observed.
9. Data can be reviewed at specific times and locations.
10. Data can be organized in ways other than by time.
11. Data tracking may not be constant, instead triggered by directed investigations.
12. Data can be reviewed in isolation or in relationship to other variables” (Beaudin et al. 2006a).

Although the charts were created to represent these health tracking concepts in visual form, discussion of the charts with participants was not limited to these twelve concepts. As a result of the interviews being participant-led (see: Section 6.2.4), different concepts were discussed in different interviews. The mock-ups were not used in piloting, but helped participants in the main study understand the scope and types of information potentially collected and shared by PHM.

8.5.2 Review

An initial sample of interviews were reviewed by the supervisory team to ensure the researcher was engaging participants in ethical dialogue which would provide data related to the research questions (see: Chapter 6). A risk existed that, because participants were given

such freedom in deciding topics of conversation, the dialogue would often stray entirely away from normative issues of PHM. It was therefore seen as the researcher's job to direct conversation back to ethical implications and moral claims (e.g. right/wrong) wherever possible, without forcing pre-determined issues and concepts such as privacy into the interview. Questions such as "How would being monitored make you feel?" or "Why does that bother you?" were used to re-focus the dialogue onto the morality of PHM for the participant. The review process was in place to ensure that the interviews were on-topic; the success of review can be judged by the quality of the dialogue concerning ethical aspects of PHM (see: Chapter 9).

8.6 Conclusion

An empirical study designed to test the conceptual framework developed above (see: Section 3.4 and Chapter 4) has been described in this chapter. The framework acts as an interpretive guide for the perspectives of participants, meaning the empirical study explores whether the framework is able to coherently explain ethical implications perceived by stakeholders in terms of colonisation. If outlying issues and concepts are found, refinement or demarcation of the framework to certain 'types' of ethical issues will be necessary. The study therefore acts as a tool of validation and refinement for the conceptual framework through which new issues and concepts not seen in the PHM ethics discourse (see: Chapter 3) or accounted for in the framework may be discovered. The empirical study described here therefore provides a data set against which the framework's explanatory strengths, limitations and areas requiring revision can be identified. The next chapter presents the results of the study, and relates them to these aspects of the conceptual framework. The impact of the study on the linkages identified between ethical themes in the reviewed literature is also considered, as these connections can help identify new or important concepts which should be accounted for in the framework. Before presenting the results of the study in these terms, the method for analysing assessing the empirical data is first reviewed.

9 Chapter 9: Data Analysis and Results

9.1 Introduction

In order to test and refine the conceptual framework for PHM, an empirical study of potential users of PHM concerning personal and medical relationships was conducted. The process of refining the conceptual framework on the basis of the empirical study can be conceived of as a discourse between the researcher and the participants in the study. Rather than accepting and rejecting the various claims made in terms of credibility or validity, the discourse only goes so far as to translate uncertain normative claims. Those found to be legitimate by the criteria described above can then be included in the framework, meaning the researcher will explain how the claim is explained by the framework. If the framework cannot account for a claim, it will instead be considered how the framework needs to be expanded. This is not to say the framework will be expanded endlessly to cover the myriad potential ethical implications of PHM, including all those seen in the reviewed literature (see: Chapter 3). Such an expansion would be necessary for a comprehensive theoretical framework of PHM, through which all of its implications can be explained. To ensure the quality of the framework, it will only be expanded to account for legitimate normative claims concerning implications for personal and medical relationships, where legitimacy is determined through translation (see: Section 7.3.2.4).

The refinement discourse is limited to determining the legitimacy of claims through translation (see: Section 7.3.2.3)—it is not a complete discourse because evaluating the credibility of claims, or moral decision-making, is not undertaken. The discourse must be limited in this way because the conceptual framework is meant to assist in future context-specific discourses relating to ethical implications of PHM—the empirical discourse in which the framework is refined does not decide on the correct course of action in a specific case, and thus does not need to evaluate the credibility of legitimate claims. This approach allows for expansion of the conceptual framework to include a variety of ethical frameworks, principles and moral values, without endorsing any particular one as correct.

While the approach taken is holistic, it is not morally relativistic (see: Section 3.1.1) because it only acknowledges the *initial* credibility of the many approaches to moral evaluation taken by participants in the study, while saying nothing of their credibility for moral decision-making in a specific case. In other words, the approach does not claim that all of the ethical frameworks

and moral values encountered in the discourse are equally credible, but rather to be useful in the future the framework must account for the various approaches brought to future discourses. The purpose of the framework is to help participants in ethical discourse understand the implications of the technology by drawing attention to implications beyond those recognised in common approaches to ethics, which emphasise privacy, autonomy or moral principles such as respect for autonomy or beneficence. In doing so the framework does not endorse any particular solution or response to potential implications; future solutions will depend upon the outcome of future ethical discourses in specific contexts of use.

9.2 Data Analysis

In order to test and refine the framework, a data analysis method complementary to the empirical methodology described above (see: Chapters 6 and 7) is necessary. Methodological choices have been made which reflect the researcher's epistemological and ontological commitments. A method of future-oriented ethical analysis has been described, along with standards of moral justification and credibility. Within this methodological framework a complementary approach to empirical data analysis is required.

The analysis of qualitative data typically involves reducing, categorising or otherwise organising the data in such a way that links or themes can be identified. Coding or "identifying meaning units" is perhaps the most common way to start analysis (Denzin & Lincoln 2000; Patterson & Williams 2002), during which the researcher reads and re-reads the texts and begins to abstract and summarise the data. The process of analysis is often iterative, opaque and without a clear methodology, but this 'inherent messiness' is not necessarily a weakness (cf. Marshall & Rossman 1999, p.153). Attempts have been made to 'clean up' qualitative research to meet positivistic ideals of rigour (Strauss & Corbin 1994; Mays & Pope 1995; Urquhart & Fernández 2006; Jones & Alony 2011), yet under the hermeneutic paradigm such attempts are misguided and harmful to the outcomes of qualitative research.⁹⁴

9.2.1 The Organising System

The central structure of hermeneutic analysis is the organising system (Tesch 1990), which provides a framework for the organisation, interpretation and presentation of the interviews

⁹⁴ For example, Grounded Theory attempts to eliminate bias by standardising the steps of data analysis to allow themes to 'emerge' from the data and not the researcher's interpretation. For more on the problems of such attempts to increase the rigour of interpretive research through the elimination of bias, see Appendix 13.

(Patterson & Williams 2002, p.45). The creation of an organising system, with categories, themes and relationships, is analogous to the process of data analysis. The final organising system is the product of data analysis, which should provide a “thick description” of the themes found in the interview data (Patterson & Williams 2002, pp.45–46). At its most basic, the organising system should structure the phenomenon under study in such a way that new insights are revealed.

The organising system which structured analysis is the conceptual framework developed above (see: Section 3.4 and Chapter 4). The data was analysed to make a distinction between claims made by participants which can be understood as effects of PHM on personal and medical relationships, and those that cannot. For claims concerning relationships, data analysis involved testing the explanatory power of the framework to ‘make sense’ of the concerns of participants, identifying limitations and potential ways to improve the framework in the process. In presenting the results of the study a clear distinction is made between findings falling within the framework and outliers suggesting limitations or areas for refinement.

9.2.2 The Steps of Data Analysis

The data analysis method used in the empirical study was inspired by the approach outlined by Patterson and Williams (2002, p.46), with modifications to address the epistemic difficulties of uncertainty.

Data analysis was carried out systematically to ensure all data was given equal consideration. This is not to say all the data was weighted equally in the researcher’s final interpretation, but rather that the steps of data analysis which led to that interpretation (coding, categorising, identification of themes and relationships) were carried out systematically and rigorously, involving iteration and revisiting texts as the researcher’s understanding of the data developed over time. As such, the findings should be taken as a fair representation of the range of data collected and themes identified. Variations on themes are presented when found in the data, and outlying cases are mentioned. A systematic method was, however, not adopted as a means of freeing the interpretation from the researcher’s influence (see: Section 6.1.1.1).

Analysis started while data collection was still underway. The empirical study was iterative (see: Section 6.1.3.2.2), meaning initial analysis was used to refine interview topics, categories and specifications of ethical concepts and principles. The interview transcripts are referred to here as ‘texts’, in line with the recognition of the applicability of hermeneutic analysis to social

phenomena and non-text sources of information (see: Section 6.1.3). For participants who completed two interviews, both transcripts are considered as a combined single text.

9.2.2.1 Step 1 – Transcription

In line with ‘best practice’ in qualitative research (cf. Crabtree & Miller 1999; Marshall & Rossman 1999), all interviews were recorded on an audio device and transcribed as soon as possible after they occurred.⁹⁵ All interviews were transcribed in their entirety, including pauses, laughter, conversational fillers (e.g. ‘umm’, ‘uhh’) and stumbling over words.

9.2.2.2 Step 2 – Initial Reading

Next, the interview transcript was read once to provide an initial understanding of the text. For participants completing two interviews the transcript from the first interview was re-read before reading the second transcript to remind the interviewer of the participant’s background and previous answers.

9.2.2.3 Step 3 – Identification of Meaning Units

Sentences were chosen as the “meaning units” for coding (Patterson & Williams 2002, p.47), or statements that, according to the researcher’s interpretation, provide insight into the phenomenon being studied. In this step sentences were identified for subsequent coding. Sentences were chosen because they represent complete thoughts or claims. Sentences were often grouped together to reflect more complex claims, or analysed with attention to their location in a paragraph and the interview as a whole so as to understand the context in which the statement was made. After an initial reading, sentences of interest for further analysis were marked in the transcript.

The meaning given to sentences was located within a holistic view of the text (Patterson & Williams 2002, p.47). Sentences identified as meaning units contained information about the participant’s personal, professional or medical background, or made reference to moral values, ethical concepts, normative claims or opinions stemming from the participant’s reaction to PHM and the scenarios posed by the researcher (see: Section 8.5).

9.2.2.4 Step 4 – Organisational Coding

The next two steps involve sorting or labelling the meaning units based on the researcher’s interpretation of the text, which has developed over the previous 4 steps, through the

⁹⁵ Two sample interview transcripts are provided in Appendix 16.

application of codes. While meaning units are the empirical statements to which codes are applied, codes are the researcher's interpretation of "what the meaning units reveal regarding the phenomenon being studied" (Patterson & Williams 2002, p.48). This type of coding is a common step in many qualitative research methodologies (cf. Tesch 1990; Strauss & Corbin 1994; Patterson & Williams 2002). Codes allow the researcher to group meaning units by common themes, content or meaning for further analysis.

In Step 4, 'Organisational Codes' (OC) were applied to the meaning units to summarise the content of each unit in the words of the participant.⁹⁶ OC served as labels for statements in need of further analysis, or those containing background, demographic or other contextual information relevant to understanding the meaning of the participant's claims (Maxwell 1998, p.237). These codes emerged directly from the data, in the sense that the participant's words were used to give each code a name. The purpose of these codes was to create a shorthand way of viewing the data in the words of the participant, allowing for comparison between the participant's literal statements and the researcher's interpretation of the meaning of the statement. These codes were not revised as analysis proceeded, so as to not lose the 'original' meaning expressed in the participant's words. OC ensured the participant's voice was retained in presenting the findings of the study, while recognising that that meaning given to a statement by a participant cannot be perfectly recreated in interpreting and coding the data.

OC were divided into two types: Biographical and Normative. Biographical OC contained content about the personal or medical background of the participant, and were referred to in finding connections between the texts of multiple participants sharing a similar experience or characteristic. Normative OC contained content related to a normative claim about PHM which required further analysis. In practice this meant that each Normative OC was assigned at least one Substantive Code in the next step of analysis.

9.2.2.5 Step 5 – Substantive Coding

Substantive coding involved the researcher interpreting the meaning of the sentences labelled with a Normative OC. Substantive Codes (SC) make claims about the data, or represent interpretations of the data, and can thus be proven wrong in a way that OC generally are not (Maxwell 1998, p.237) because the latter are intended to be a shorthand summary of the

⁹⁶ Tone, speed of delivery, sarcasm and emotions in the audio recording of participants cannot be easily represented in transcripts, yet these elements can radically change the researcher's interpretation of a meaning unit. In recognition, the interview was played back while coding the data.

participant's words rather than a meaningful interpretation of the words by the researcher. Substantive codes are the researcher's interpretation of the data and are iteratively revised as analysis proceeds by revisiting texts throughout the analysis process. Ideally, codes become increasingly specific as analysis progresses, showing that the researcher's understanding of the data is developing. The researcher's interpretation is based on his preconceptions (Maxwell 1998, p.237) of PHM (as seen in the framework of ethical issues, concepts and values developed in Chapters 2 and 3), and his familiarity with each participant developed through the interviews themselves as well as reading and re-reading the interview texts and field notes. SC went beyond the words of the participant and brought in themes from the conceptual framework and literature review such as privacy, surveillance and data control review (see: Chapter 3), although SC went beyond these themes and concepts when the meaning of the participant's statement did not match either. In this way substantive coding was guided by but not limited to the conceptual framework and literature review.

SC were assigned by reviewing each meaning unit assigned a Normative OC (see: Figure 9.1). In this way the participant's words influenced the researcher's interpretation of the participant's statements. This aspect of coding prevented the researcher from 'forcing' units into his framework of prejudices.

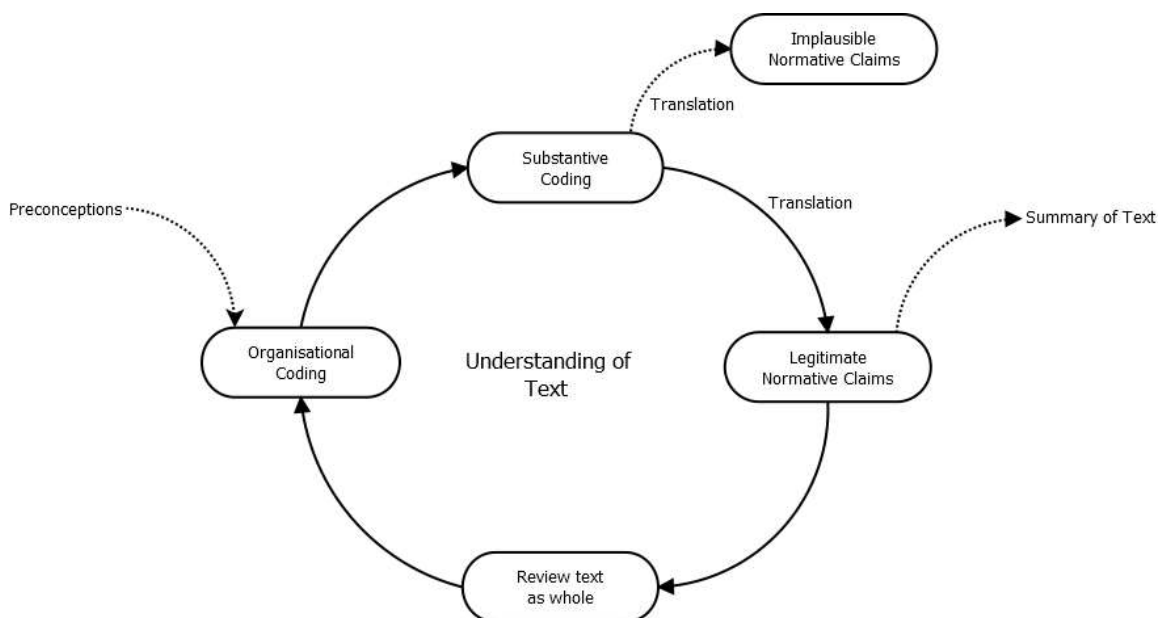


Figure 9.1 - Iterative Analysis of a Text

Coding was iterative, meaning codes were shared across the sample, texts were revisited, and codes were revised, further specified and grouped as analysis progressed (see: Figure 9.2). In practice, meaning units for a single code were frequently reviewed and revised as contradictory meaning arose within a single code, necessitating the creation of two or more new, more specific SC. The concept of meaning units as presented in Patterson and Williams (2002) is somewhat problematic, as sentences are described as “complete thoughts,” implying a sentence has a single clearly defined meaning. In research in which participants are exposed to unfamiliar phenomena such as PHM, contradictions and incomplete thoughts should be expected as the participant comes to understand the new technology.⁹⁷ Recognising this, multiple SC were often assigned to a single meaning unit to show different possible interpretations, reflecting the fact that meaning units are not subject to a single ‘correct’ interpretation.

Participants occasionally shared experiences that revealed an interesting aspect of their background as a caregiver, patient or healthcare provider. Although not explicitly a claim about PHM, these types of statements were important in understanding the meaning behind the participant’s other statements.

9.2.2.5.1 Step 5a - Translation⁹⁸

To assess the legitimacy of claims made during interviews, translation occurred during substantive coding. Translation is both a description of how uncertain normative claims are evaluated in a discourse, and a procedural step to be undertaken in substantive coding. The procedure required identifying the ‘normative truth content’ of claims made in a discourse about uncertain future events. Legitimacy was assessed according to the components of an uncertain normative claim described above, concerning characteristics of a particular future, the participant’s reaction to it and the values grounding the reaction (see: Section 7.3.2.5).

To ensure the normative truth content of a translated claim is as accurate as possible, flaws in the participant’s description of the future were discussed whenever possible during the

⁹⁷ Contradictions may also signal an ethical tradeoff or ‘inherent duality’ (see: Section 3.3.2). Contradictions were practically useful in the sense that they indicated topics the researcher should probe further during interviews. Incomplete thoughts and contradictory positions are important in this regard to hermeneutics dialogue as a process in which participant and researcher interpret and discuss unfamiliar phenomena, hopefully emerging with a ‘fusion of horizons’ in which both have reached a novel understanding of the phenomenon under discussion.

⁹⁸ Translation is only necessary when researching ethical aspects of potential futures, whereas the rest of the analysis method is applicable to other types of qualitative hermeneutics research.

interview to ensure the reaction of the participant was not based on fantasy or misinterpretation of the technology's potential. Factors that may have changed the participant's reaction were also discussed, such as the (mis)match between patient values and the strategies of medical institutions and clinicians concerning PHM (see: Section 5.2), the expectations of patients regarding 'good' healthcare, and the potential uses of the technology. The role of telehealth and telecare in DH strategy was discussed with some participants to ground the discussion in potential implications within the English context.

Translation helped eliminate uncertain claims based on misunderstandings of the potential of PHM or descriptions of how PHM may be used in the future which lacked even a minimal grounding in current development or NHS strategy. With such 'implausible normative claims' separated, the remaining 'legitimate normative claims' were understood as reactions to potential futures with at least minimal plausibility. Following this, translation was completed by assigning substantive codes to the claims describing the participant's reaction to a potential future and, whenever possible, the value(s) underlying the reaction according to the participant's responses to questioning in the interview.

Substantive coding and translation marked the final steps in the analysis of any single text. A visual representation of the analysis of a single text can be seen in Figure 9.1. A brief summary of the issues, concepts and claims made by the participant was written after analysing each text. The following steps moved on to comparing codes and identifying relationship between multiple texts.

9.2.2.6 Step 6 - Grouping

During and immediately following the substantive coding of a text, initial groupings of SC consisting of legitimate normative claims were created and iteratively revised as analysis proceeded, using headings such as 'privacy', 'clinical relationship', 'data processing', 'surveillance' and other elements of the conceptual framework and themes identified in the literature review. The purpose of grouping was to iteratively identify relationships between the codes as the researcher moved between texts to assist in further analysis and the identification of new insights in the next step of analysis (see: Figure 9.2). Groupings were reviewed after coding or revisiting each text.

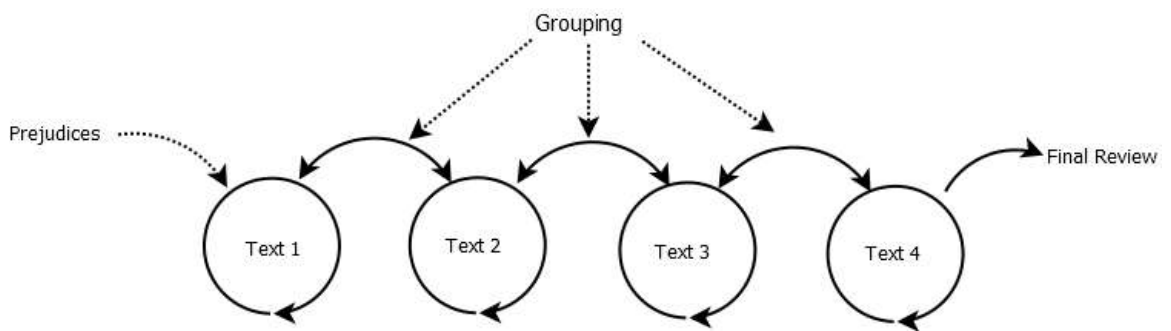


Figure 9.2 - Iterative Analysis of Multiple Texts

9.2.2.7 Step 7 – Final Review and Identification of Outliers

During final review, SC were placed into final groupings created from the conceptual framework and results of the literature review. An ‘outliers’ group was created to account for claims which could not be understood through the conceptual framework or themes from the literature review. In this way the increasingly specific SC were reconstructed into meaningful groupings that revealed possible approaches to understanding the meaning of a particular ethical issue or concept according to participants. The strength of this approach is that it requires a clear distinction for claims concerning relationships between those which are explicable within the conceptual framework, and those outliers challenging its explanatory power.

9.2.3 Discussion of Analysis Method

As hinted at in the figures above, the method of data analysis can be understood as a hermeneutic circle (see: Section 6.1.3.2.2), meaning data collection and analysis were iterative. The hermeneutic circle describes the structure of the hermeneutic dialogue which occurred during data collection and data analysis, in which the researcher's preconceptions and the phenomenon studied interact (Patterson & Williams 2002, p.27). The structure of analysis as presented in Figures 9.1 and 9.2 shows a type of hermeneutic circle, in which the researcher’s understanding of potential ethical implications of PHM concerning personal and medical relationships develops iteratively through analysing and revisiting the texts of local practitioners. In this sense the hermeneutic circle is a name given to hermeneutic data analysis, which proceeds through a simultaneously holistic and deconstructive reading of a text. A holistic view of the text provides an initial understanding of the phenomenon to the researcher, and informs the interpretation of separate parts of the text (Patterson & Williams 2002, p.27). The process becomes a circle when the interpretation of separate parts of the

text leads to re-interpreting the text as a whole, and the interpretation of other texts leads to reinterpreting the original text.

9.2.3.1 *Reviewing Hermeneutic Interpretation*

Although all forms of interpretive research recognise the inherent subjectivity of explanations of the world, validation, or the search for common ground between these explanations that convince us of their credibility, cannot be abandoned entirely if pragmatic evaluations of the relative credibility of research are to be possible. Particular interpretations cannot be seen as absolutely or objectively true—hence the picture of understanding as a never-ending circle in which the understanding of a phenomenon improves through endless openness to new interpretations and evidence. Despite never arriving at static conclusions, hermeneutic understanding (and research) can facilitate ‘cooperative life’ by establishing mutual understanding through dialogue (see: Section 6.1.3).

Recognising this, some form of review was required if the analysis of the empirical data is to be seen as reliable and persuasive (see: Section 6.3.2). Interpretations of claims can be more or less credible according to how close the researcher’s interpretation comes to the ‘original’ meaning of the participant, supported by the text itself and the participant’s other claims. Review steps were built into analysis to force the researcher to compare his interpretations of the meaning of the participant’s statements against the participant’s actual words.

Review occurred in three ways. First, in the analysis of any individual text, substantive coding was not the endpoint. The text was re-read as a whole to check that the researcher’s substantive codes represented a reasonable interpretation of specific statements within a holistic view of the text. Second, as substantive codes were revised and grouped across multiple texts, individual examples of each code were compared against the matching organisational code to check that the revised code or grouping still matched the participant’s words. When it did not, either a new substantive code was created or a note was made which explained the reasoning behind the researcher’s interpretation despite the mismatch. Third, the researcher’s coding was reviewed by the supervision team to ensure the coding represented a reasonable interpretation of the data, even when other plausible interpretations were identified. The possibility of alternative interpretations is to be expected among individuals with different backgrounds which provide a different ‘lens’ through which the data can be viewed. The review process ensured that alternative interpretations of the

data were considered, helping the researcher to arrive at increasingly credible interpretations of the data through dialogue with reviewers.

Credibility as used here is not a synonym for 'true'. Rather, it means that the researcher's interpretation matches the words of the participant in some way. As an example, the statement "I am a very private person" uttered in response to a question about being 'watched' by a camera could be reasonably interpreted as meaning "I value being left alone," or "I value my independence from others," or "I don't want to be watched" if it was uttered in response to a question about surveillance. Interpreting this same statement as "I dislike the company of others" or "Privacy is my most important value" is less reasonable because the statement does not compare the relative importance of particular values or refer to social attitudes beyond the immediate topic of dialogue (surveillance). Reasonable interpretations rely upon an understanding of the text as a whole and the participant as a socially embodied person with a particular history and set of values. Supporting arguments are required when interpretations vary significantly from the actual words uttered by the participant.

9.2.3.2 Theoretical Outliers in Coding

Coding with two types of codes to separate the participant's voice from the researcher's voice facilitates reflexivity in the presentation of results. OC and SC can be understood as the difference between the researcher describing the participant's world as accurately as possible for the reader (imperfect as this account necessarily must be), and the subsequent interpretation of that world within a specific framework of prejudices. This is not to suggest the former is objective and the latter subjective; the researcher's prejudices necessarily influence any encounter with and interpretation of the participant's lifeworld. Instead, the difference is that SC attempt to fit the participant's statements into the researcher's framework of understanding so as to identify outliers or unfamiliar experiences and interpretations which can subsequently expand the conceptual framework beyond its current limitations.

9.2.4 Conclusions

The data analysis method described above allows for fair consideration and questioning of uncertain normative claims in discourse (see: Figure 9.3). The outcome of this method for data analysis is testing and refinement of the conceptual framework concerning ethical implications of PHM for personal and medical relationships. The purpose of the study was to identify the

current limitations of the conceptual framework. Recognising this, the discussion of results distinguishes between claims about relationships which can be explained within the current conceptual framework and those outside its boundaries which indicate limitations or a need for refinement.

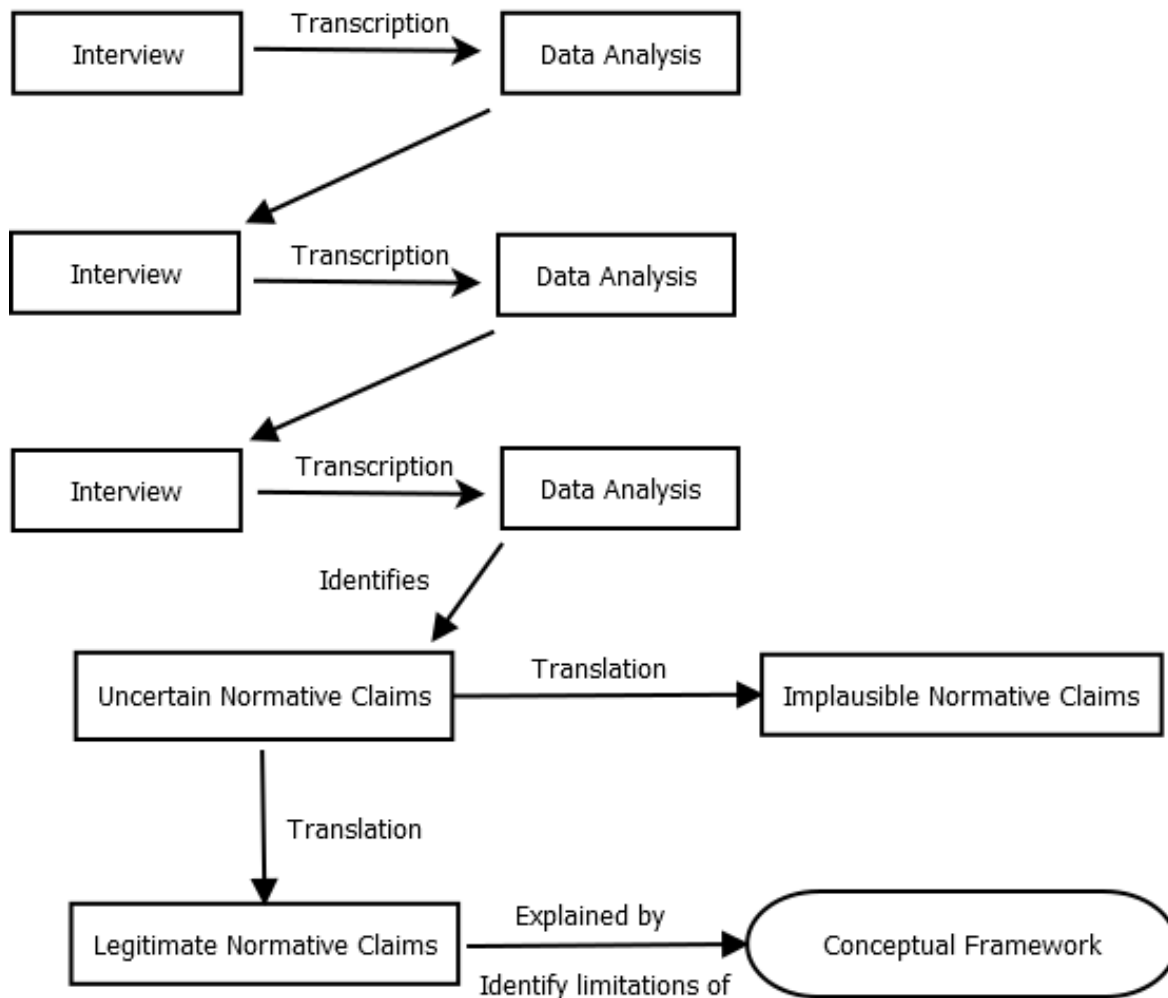


Figure 9.3 - Data Analysis Method and Outcomes

9.3 Results

As the approach to data analysis taken here is based in hermeneutics, a clear distinction between ‘results’ and interpretation or ‘discussion’ of results would be inappropriate; instead, analysis of claims made by participants are considered alongside the claims themselves. Interpretive presentation of empirical results has been called for in qualitative hermeneutics research (Patterson & Williams 2002, p.63). In line with the ‘persuasiveness’ quality criteria described above (see: Section 6.3.2), the quotes and summaries of the data presented here are

meant to show how the researcher reached his interpretation of the claims made by participants.

The results are discussed from the perspective of ethical implications of PHM on personal and medical relationships. In practical terms this means that wherever possible participants' claims are related back to relationships and the conceptual framework. Not all of the claims made by participants can be understood in terms of implications of PHM on relationships. In itself this was not a surprising result because interview topics were participant-led (see: Section 6.2.4). The presentation of results is limited to those claims which relate to ethical aspects of personal and medical relationships mediated by PHM. Results concerning relationships were considered within the conceptual framework. Connections between the framework and results are identified in terms of the framework's ability to explain the concerns expressed by participants. Where the framework lacks explanatory power, the need to refine the framework on the basis of the claims of participants is considered. The need for refinement is identified whenever a legitimate normative claim about PHM-mediated relationships is encountered which cannot be explained within the conceptual framework in its current form (see: Chapter 7).

9.3.1 Self-Care vs. Improved Care

PHM was viewed by many participants as justified if it benefits the user's medical care. A common assumption was that PHM data would be sent to the GP to improve the user's care, which justified its adoption:

DP4: "That would be okay because basically he's [the GP] here to help me, so anything I can do to help him to help me, it's got to be a good thing, doesn't it?... I can see that is to my benefit, because if they weren't happy with any of that, I assume that they'd go right to me and say you need to make an appointment...I can't really think of anything that a monitor would monitor that I may not want them to know, because I just feel at the end of the day that it's to my benefit."

DP1: "Well, yeah, because he's treating me, he's trying to make me better. What's the point of him not knowing what I'm really doing?"

The position taken by **DP1** suggests that monitoring in the patient's lifeworld is justified because it provides clinicians with a better, or more complete, picture of the patient's health, tracked through physiological and behavioural monitoring. The assumption that PHM is primarily used to improve medical care conflicts with the strategic justification for monitoring concerning efficiency, where (technologies enabling) shared responsibility for medical care are

increasingly valued (see: Section 5.4.1.2). Evidence of the strategic movement towards self-care seen above was seen in the responses of some of the professional participants. PHM was described as a tool to provide increasingly interactive services to patients:

CC2: "It's being able to work with patients to create a capacity, a service by which we can all work together to manage the condition."

CC3: "There is scepticism in the UK about using health monitoring systems and actually delegating care to patients, to be much more involved and responsible for their care. So we've moved away I think in the UK from a paternalistic model of care to much more engagement."

CC3 described this movement towards patient engagement as desirable, with PHM being one tool among many to encourage personal responsibility and self-care. **CC2** believed PHM helps patients take control of illness management and medical relationships by being able to contact their care team when something is wrong, either according to how they feel or to the readings taken by PHM. This attitude is informed by her experience managing a telehealth programme for COPD patients, which involved regular contact with a nurse practitioner via a screen connected to the device. The potential for PHM to increase contact with health professionals cuts both ways—patients may have an easier time contacting providers, but providers may simultaneously be overwhelmed by requests from patients (for example, based on worries relating to normal fluctuations), inhibiting the prioritisation of provider time for the 'neediest' patients. While it is assumed in strategy that patient engagement leads to better health outcomes, the potential for PHM to overwhelm care services through patient engagement and data collection suggests controls are necessary to limit the newly created burdens placed on clinicians and institutions to protect against reducing the quality of care provided.

9.3.1.1 Patient Feedback

A central component of self-care which gives rise to the above risks is personalised feedback based on PHM data, which was seen as desirable by five patient participants due to the possibility of personalised recommendations for illness management outside of clinical encounters. Feedback was seen as improving the user's feeling of controlling their illness, quite apart from whether physiological changes actually result from lifestyle modification, because it allows for comparisons between perceived and actual behaviours as captured by the system. As explained by **DP3**, a 'behaviour log' allows the patient to identify inconsistencies between perception and reality in terms of, for example, miles run, calories

eaten or time spent on the couch. With that said, feedback does not automatically improve illness management or increase motivation for self-care:

DP1: “Do you think people would use it for that? Because people, I mean, I know people who've got the machines now that test the blood and do the strips. And they monitor their sugar levels are high but they don't actually do anything to rectify it.”

In contrast to the supportive attitude shown by many participants towards feedback and self-care, as suggested by **DP2** feedback may be seen as ‘nagging’ by individuals less motivated to change their behaviour in response to a health condition. These claims suggest PHM may be welcomed by motivated patients as a tool of self-care or reassurance, but seen as annoying by others.

Feedback may also contribute to health obsession in users (see: Section 3.3.5), particularly if users can access raw data rather than clinical analyses of the data (see: Section 9.3.3.1). **HP1** and **HP5** felt ‘always-on’ blood pressure monitoring should only be offered as a temporary measure because of the potential for users to become obsessed with minor fluctuations in readings. Similarly, **DC5** felt preventative monitoring would lead to paranoia and health obsession, saying that in some cases “the less you know, the better” because you worry less about potential health complications. **CC1** mirrored this sentiment, saying PHM can ruin this “happy ignorance” by revealing unknown health conditions or showing that a treatment or lifestyle choice is not as helpful as originally thought.

9.3.1.2 Information Overload and the Burdens of Providing Feedback

PHM may improve relationships with patients by collecting clinically relevant data (**DS1**). This line of reasoning is only coherent if the data provided by PHM can be incorporated into clinical encounters effectively, meaning sorting and analysis does not overburden the clinician. The potential for information overload was recognised by all of the disease specialists and care commissioners as a serious risk associated with PHM—primary care is said to already be “drowning in data” (**CC1**). The risk is so great because without effective data handling feedback cannot be provided to patients, degrading the healing relationship:

CC1: “The more data we generate, the implication is that somebody's going to do something, somebody's going to look at it and do something with it and it only becomes meaningful when you attach a meaning to it...what's concerning for everybody is the idea that if we deploy at scale a variety of devices and people are doing as we ask them to do, that is ‘I'd like you to use this device, I'd like you to upload some of your data’, then the implication is that somebody's going to look at that and

somebody's going to analyse it and evaluate it and attach a meaning to it, and that consequent upon that meaning being identified somebody's going to feedback to the patients."

Questions were raised by patients regarding the capacity of clinicians to analyse the data:

HP3: "Would my GP want to look at it? [pause] You know, if all the patients had something like this, he'd spend all his time looking in the screen, wouldn't he? Different data for different patients. Would he bother to do that, do you think?"

DP4: "And there's no chance of them checking it [PHM data], because you saw how busy GPs in the surgeries are, because they'd be annoyed if you sort of did it, and then they just said, oh, that, yeah, well we haven't got time to look at that."

An example of the burden created by PHM data can be seen in current handling of glucose monitoring data. According to **CC1**, when glucose readings are brought to a clinical encounter by patients they are rarely analysed by the clinician due to a lack of time—"there's a big loop there to be closed, that's a real concern." This problem can be transferred to PHM which provides users with greater quantities of clinically relevant readings. As mentioned by **DS2**, the burdens of processing PHM data create a need to "pass responsibility to patients" for care wherever possible.

9.3.1.3 Decontextualisation and Access to Medical Records

Other practical risks relate to how PHM data is treated by care teams responsible for remote monitoring, assessment and feedback. Unless PHM is deployed in a "clinically coherent" way, it may create more work and make the patient more anxious without actually delivering on efficiency goals in terms of hospital admissions or other factors (**CC1**). Concerning the possibilities for decontextualisation created by PHM, **CC1** felt that clinicians assessing PHM data will require access to the user's complete care record to account for effects of other medical conditions or history. The patient may have other conditions or symptoms unrelated to the condition for which they are given telehealth. Any deployment of telehealth requires complete clinical information so that correct meaning can be attached to the readings. As a result, patients may be forced to accept further sharing of personal health data to ensure assessment of PHM data is personalised to the patient's unique medical history.

9.3.1.4 Losing the Socially Embodied Patient in Commissioning PHM

CC1 described how commissioning operates with regards to determining the cost-effectiveness of a device used to justify its usage. The costs of certain outcomes such as emergency

admissions are clearly measurable so the outcomes of PHM in this regard can be computed and figured into business cases. Things that cannot be 'costed' so easily, such as the 'value' of human touch and speech or the quality of a clinical encounter, are more difficult to 'weigh' against other outcomes of PHM and may be given less importance when choosing how and when PHM will be adopted through commissioning. This aspect of commissioning suggests that social, emotional and psychological aspects of health and medical care do not inform institutional decisions to use PHM to the same degree as cost-effectiveness factors. This situation creates the possibility for unjustified deployments of the technology inappropriately matched to contexts of use, and can be seen as an example of decontextualisation in technology deployment or care commissioning. The danger presented is that monitoring may be seen as justified in terms of costs, when aspects of health care that cannot be easily costed have not been given fair consideration in the decision to deploy monitoring because they cannot be conceived of in terms of quantities or cost-effectiveness.

9.3.1.5 Improved Clinical Outcomes and Ethical Tradeoffs

By introducing PHM into medical relationships for the sake of efficiency, NHS health professionals and medical institutions may be forcing users into adoption decisions characterised by ethical tradeoffs (see: Sections 3.2.3.1 and 3.3.2). Among participants who hypothetically agreed to adopt PHM when asked, most saw monitoring as justified when it makes a clear difference to the health of the user, meaning health (or safety) overrides the ethical concerns seen above relating to control, privacy, autonomy, medicalisation, behaviour inhibition and other concerns expressed in the study. For example, **DC5** was troubled by a perceived loss of privacy through monitoring, but saw it as justified for her husband whose dementia justified the intrusion. For her, being monitored for health is being monitored “for the right reasons.” **DP1** similarly saw monitoring as violating her privacy and the privacy of people entering her house, but felt its benefits in terms of providing behavioural feedback and potentially improving self-management of her diabetes outweighed these problems (cf. Courtney et al. 2008, p.198). **HP4** expressed the tradeoff as the “intrusiveness” of physiological monitoring being justified if it provides her GP with a better idea of why her BP is high.

CC1 spoke of an “unspoken psychological contract” which exists between patients and clinicians when entering into medical care, described as a type of “bargain” in which the patient relinquishes private information to the clinician for medical care:

CC1: "It's something peculiar about the nature of healthcare, we make those bargains all the time, we give up a certain amount of autonomy or independence or privacy or in some cases a little bit of dignity, and we imagine that the tradeoff is that this is part of what's necessary for me to either be reassured about my health or actually treated or monitored...it's an interesting question how we sell these things at the outset. We have a negotiation that goes on when we introduce the device...there probably needs to be some kind of conversation."

The bargain described is similar to the healing relationship described above (see: Section 4.3.2.1). PHM is seen as requiring the same type of bargain in which the user must "accommodate the device" to receive care. **CC1** compared PHM to existing intrusions by district nurses into the homes of patients requiring in-home care. Such intrusions (PHM included) are justified because the nurses, or PHM, are there "by invitation," meaning the user consents to their presence. A clear connection can be seen with ethical tradeoffs described above (see: Section 3.2.3.1), although this sort of bargaining was rarely mentioned by participants in the study.

9.3.2 Surveillance

Many of the claims raised by participants can be understood within theories of surveillance included in the conceptual framework (see: Section 4.4). Patients overwhelmingly expressed concerns over surveillance and cameras through invoking 'Big Brother', which was identified earlier as an inappropriate metaphor of PHM (see: Section 4.4.1). For example:

DC1: "I have quite contradictory reaction to it, to be honest. Uhh..on the one hand, it sounds very Big Brother, you know, '1984' (pause) and I can see that it could be seen as an invasion of someone's privacy and then also, dignity for people."

By definition 'Big Brother' refers to a centralised form of surveillance; in Orwell's 1984 surveillance is carried out by the four government 'Ministries' to monitor and control the thoughts and behaviours of citizens. In transferring the metaphor to medical care in England, patients appear to be envisioning centralised surveillance carried out by the NHS or the government unified under a single organisational hierarchy. In reality, the implementation of PHM is heterogeneous, carried out by diverse NHS trusts, CCGs or other medical institutions (see: Section 5.3) with only strategic support for diffusion being centralised (see: Section 5.2). In part this confusion may be explained by patient ignorance of how commissioning and diffusion processes work in the NHS, seen for example in **DC1**'s concern that "some nebulous person" would hold be able to collect and store data about her via PHM. However, the view of centralised surveillance taken by patients may be realistic if data is increasingly centralised by

the NHS for cost-savings or security (e.g. Department of Health 2010b). If centralised databases are also searchable, surveillance is increasingly possible. Similar outcomes are possible if care commissioning is increasingly centralised, for example through adherence to NICE guidelines (see: Section 5.3).

A perception of being watched was connected to the Big Brother metaphor. **DC5** described monitoring behaviour and health patterns as a “bit like Big Brother watching you.” **HP3** thought monitoring would be “intrusive” because “you couldn't do anything without being monitored all the time.” **HP4** identified problems specific to behaviour monitoring, describing it as “weird” because “it's a bit like Big Brother watching you.” Similar concerns were not expressed over blood pressure monitoring, despite recognising that physiological monitoring is “the same.” **DP4** described monitoring as “feeling kind of like being watched 24/7,” despite recognising that it may be used for her benefit. Similarly, **DC1** thought that monitored individuals “would think they are being watched all the time” to monitor adherence to recommended interventions, such as an exercise regime.

9.3.2.1 Behaviour Modification

The perception of being watched was perceived by participants as inhibiting their autonomy or behavioural freedom. Many participants claimed that the feeling like they were being watched through the monitors would cause them to change their behaviour in response, similar to what was described as colonisation above (see: Section 3.4.1):

DC2: “You wouldn't want to think that people were looking at you in your own home. And, so if, if someone's looking in your home, then you feel that you have to do something differently.”

Environmental monitors were seen as ‘controlling’ the user, meaning the monitoring system was seen as inhibiting decisional and behavioural freedom:

DP1: “I'm not the sort of person that likes to be controlled. You know what I mean? I like to know what I'm doing and be myself, be able to sort things out without interference.”

DP3 claimed that monitors would prevent her elderly father “from relaxing, from being himself” in his home. She went on to say PHM would feel like “Little Brother” or a third person constantly present in the home, comparing it to staying in someone else's home or acting in different ways depending on who is in her house: “As much as they want you to be relaxed...you are different.” This inability to relax in the home was described as a form of

stress induced by monitoring, and was a main reason why **DP3** rejected the prospect of monitoring the home with environmental monitors.

The potential for behaviour modification was not seen entirely negatively, as suggested by enthusiasm for personalised feedback contributing to desirable changes in lifestyle among users (see: Section 9.3.1.1). For instance, **HP4** thought monitors may have a positive effect on behaviour by making users more active if they feel they are being watched. Similarly, providing PHM data to clinicians was thought to create a pressure on patients to adhere to treatment recommendations. The pressure would not necessarily be unwelcome or change **HP4**'s relationship with her GP.

9.3.2.1.1 Acclimation to PHM

Although PHM may initially inhibit behaviour due to the perception of being watched, the effect of PHM on behaviour may fade over time as the user 'gets used to' PHM (see: Section 3.2.4):

DC2: "It's sort of somebody in your home, I suppose. I don't know. Yes, I suppose you wouldn't be acting naturally, unless, of course, you got used to it after a time, like everything."

DC5 and **DP4** made similar claims, with the latter comparing PHM to a smart water meter which causes the person to use less water (or change their behaviour) when first installed, but after a time the user will "forget it's there." Once PHM has been 'forgotten', normal behaviour may resume:

DP4: "So I think you can live more normally once you've got accustomed to having it there. You know, rather than thinking, better be careful cause I've got the camera there."

DC1: "I suppose in time, you'd forget the cameras were there and you'd behave perfectly normally."

An interesting aspect of the concerns relating to behaviour modification is that PHM was often described as a 'camera'; five participants specifically mentioned that cameras were not acceptable as part of a monitoring system, distinguishing visual data from other types of data collected by PHM. In comparing PHM to CCTV, the 'camera' metaphor suggests PHM requires a human operator or 'watcher' to work. For instance, **DP3** saw PHM as "other humans beings monitoring and discussing and watching" the user, which implies that an interested human watcher will be on the other end of the monitor either actively watching or analysing the

incoming data. This perception conflicts with the worry that GPs will not have time or a desire to analyse PHM data as seen above (see: Section 9.3.1.2).

9.3.2.2 *Social Sorting*

Social sorting, or categorising users according to PHM data which may fail to present a full picture of the user's situation, was recognised as a problem by commissioners. **CC1** agreed that social sorting is a potential risk for PHM, meaning a patient's identity may be affected in terms of self-identity or how the patient is viewed by health professionals if patients are sorted (for example, in PHM trials) according to pre-existing groups defined against clinical characteristics. According to **CC1** it is not always clear whether commissioners create "silos" or categories into which patients are forced because they fit the aims of the commissioners, or whether these groups are well-defined against clinical evidence. Providing someone with PHM designed to treat a certain type of patient (or as part of a programme targeting certain patients) classifies them as, or causes them to be viewed as an example of, that clinical category. This in turn has implications for the identity of the user, who may come to identify as that categorisation, which may be influenced as much by the politics of commissioning as it is by clinical realities. This problem can be understood as impinging the user's ability to control self-identity; PHM data allows for the patient to be increasingly clinically categorised, colonising the patient's identity with medical concerns and limiting how they are treated by medical professionals with access to their medical record. Patients come to be seen and treated 'as' a certain type of patient.

According to **CC2**, the greatest potential for PHM to contribute to categorisation of patients exists in relation to systems currently used for risk stratification by GPs. If PHM data can be 'fed' into these systems to help in identifying risk factors, the potential for PHM data to be connected to existing health records and used to categorise patients into clinical categories greatly increases. As argued above (see: Section 4.4.3), the categorisation of patients according to risk is problematic in the sense that it limits the choices available to patients and contributes to colonisation of self-identity with medical concerns.

9.3.3 *Control*

The themes identified thus far have been explicable within the conceptual framework. In contrast, a recurring theme throughout the data which suggests limitations of the framework is how PHM affects 'control' exercised by patients, clinicians and institutions in relationships.

Control is related to power in personal and medical relationships. In exercising control over PHM or its data users are inhibiting the actions of others towards them; a comparison with patient empowerment in doctor-patient relationships is appropriate (cf. Emanuel & Emanuel 1992). For instance, if a user chooses to switch a monitor off for a period of time, data custodians are denied information about the patient during that period, meaning the patient cannot be evaluated.

Control can relate to physical control over PHM systems, the collection and transmission of data including when and how monitoring occurs and how the data is used in medical care, and the shifts in power seen in PHM-mediated relationships in which stakeholders gain greater relative access to information or opportunities to influence the behaviour of others. PHM was seen in several contexts as enhancing the user's ability to control or manage their illness through monitoring physiological parameters and the effects of interventions, for example as mentioned by **DP1** in relation to PHM providing real-time glucose monitoring. For **DP2** using PHM would be justified if it allowed for earlier preventative measures or interventions, for example by providing an earlier warning of a hypoglaecemic attack. In this sense control is linked both to illness management and the perceived benefit to the health and safety of the user.

9.3.3.1 Empowerment and Honesty

Control can contribute to patient empowerment in the doctor-patient relationship. Three participants viewed unrestricted user access to PHM data as a necessity in maintaining control over the doctor-patient relationship, meaning the patient would be on an equal playing field in terms of access to evidence used in support of a diagnosis or treatment recommendations. This is not to say patients require access to potentially confusing raw data—rather, data should be provided matching the patient's level of expertise. For **DP2**, who has extensive experience with home glucose monitoring, access to the raw data provided by a PHM glucose monitor was seen as necessary to provide him with an equivalent evidence-base for argumentation when disagreements occurred with his physician. This concern presupposes a model of the doctor-patient relationship in which the patient is an equal partner in decision-making (cf. Emanuel & Emanuel 1992), rather than the patient deferring to the expertise of the physician as a matter of practice. For **HP1**, access to simplified PHM data via a blood pressure chart mapped across 'normal' ranges (e.g. Appendix A15.1) was seen as acceptable because it would allow him to locate where exactly in the 'normal' range his readings fell. A similar attitude was evident in

DP1 who prefers “specifics to a general ‘You’re OK’” when monitoring exercise as part of her current treatment regime.

In all three situations access to the data empowers the patient by keeping the doctor ‘honest’ in the healing relationship (see: Section 4.3.3), meaning the patient is provided with sufficient data to understand and question the doctor’s assessment. **DP1** saw PHM data as allowing her to question her GP’s assessment of her blood pressure:

DP1: “Do you know what I mean? I-, I would be interested in it all, that's the thing. Umm, so, yeah, I mean, I don't think I would be happy with, 'Your blood pressure has been OK for this month.' Uhh, because OK can be top of the OK range, it could be lower.”

HP1 thinks this use of PHM data can help “keep doctors honest because they won’t say something is fine when a reading is not.” This type of empowerment is interpreted as a form of control because in negotiating access to his data, the user is learning what the monitoring system is telling others about his health and behaviour. Access to data is seen as necessary to feel “in control” of the relationship, meaning the patient is in a better position to understand and question the physician’s assessment. Although physicians may wish to limit user access to data to safeguard patients from making bad decisions without the input of a clinician, for **DP1** this model of data access is ethically problematic because it takes control of the relationship away from the user.

Alternatively, PHM data can be used to keep patients honest in clinical encounters by demonstrating whether they have done what they claim, limiting the patient’s ability to lie to clinicians. In this sense the patient’s account is controlled by the physician, again forcing an honest discourse. For **DS1** this aspect of PHM may prove very beneficial to clinical encounters because it allows clinicians with limited time to prioritise care to patients willing to ‘make an effort’ and follow recommendations. According to **DS1** clinicians already know that patients lie in clinical encounters but often lack a way to broach the subject—PHM data could therefore provide a means for identifying inconsistencies in the patient’s verbal account “allowing an honest discussion.” Honesty would be beneficial for patients in terms of health outcomes while allowing clinicians to prioritise time to needy patients. **DS1** went as far to recommend specifically monitoring treatment adherence, allowing for consequences for non-adherence in clinical encounters. However, **DS1** was doubtful that patients would initially understand that PHM provides clinicians the opportunity to identify lies. While this could potentially violate

the patient's 'right' to lie to clinicians, for **DS1** and **CC1** the need to consent to monitoring means the patient is also consenting to having their ability to lie reduced by sharing PHM data with clinician—however, this position is only tenable if consent is truly uncoerced.

This attitude towards the patient's right to lie is problematic because it does not recognise the patient's need to hide embarrassing or sensitive information, which is instead revealed by PHM. By taking away control over what data is shared, PHM is potentially embarrassing or distressing the patient. Furthermore this position presumes forcing the user into a tradeoff between monitoring and controlling dissemination about one's behaviours is ethically acceptable. This effect of PHM can be seen as reducing the patient's control over their verbal account to clinicians by providing an alternative set of data for evaluation of the behaviours of the patient outside of the hospital or GP office, while potentially improving diagnosis and treatment by preventing unjustified increases in medication doses due to perceived ineffectiveness based on the patient's verbal account, for example. For **DP2** the patient must be provided equal access to their data so that the patient has evidence to argue from when disagreements occur.

9.3.3.2 The Need to Disable Monitoring

Control was also seen in relation to physical control over monitors. The simple ability to switch off monitoring is central to maintaining control over PHM. Four participants identified an 'on/off' switch as a necessary feature because it would allow them to disable monitoring when desired, allowing the user to retain a sense of control over the home, for example by disabling monitoring when family members or friends are present:

DC1: "The other thing I think you see is, that there will be occasions when there's not just you, the person with dementia and the carer in the home. There will be instances when friends will be visiting or relatives, or, you know. Uh, and, again, you know, is it an invasion of that privacy?"

Disabling monitoring was linked to lessening privacy concerns by **DC1** and **DC5** by allowing the user to switch off data collection during private or embarrassing moments. Concerning the type of data collected, **HP3** felt a "cut-off point...an area that you don't go beyond for personal reasons" would be required to prevent monitoring users at inappropriate times, such as in bed or in the bathroom, which could be accomplished through pre-defined temporal or spatial limitations on monitoring, or a manual on/off switch. For **HP1** the ability to disable monitoring,

described as a “correct safeguard” that should be built into monitoring systems, is equivalent to the user “having control over the monitors.”

The ability to switch off PHM may compromise the integrity of data or analysis reliant upon changes to physiological parameters over time, meaning its inclusion would create a conflict between personal interests in control and clinical interests in high quality data. In other words, each time a user switches off monitoring the quality of service may be degraded. Whether uninterrupted data collection is central to quality of service remains to be seen; frequent but not constant collection of BP readings, for example, may provide a sufficient basis to track fluctuations throughout the day and assess the effectiveness of pharmaceutical or behavioural interventions.

9.3.3.2.1 Inadvertent Monitoring

A preference for wearable monitors may follow from the need for an on/off switch (see: Section 2.3.3). According to **DC1** wearable monitors would be “personal to” her and less likely to be “intruding on anyone else.” Wearable monitors were seen as easily removed or disabled compared to environmental monitors:

DP1: “I would prefer to wear something because then I would feel it wasn’t as intrusive because if it decided I didn’t want to use it, I could take it off... I feel as if it’s not in my control if it was in the house whereas if it was on me, it’s in my control... I think control would be an issue for me.”

Inadvertent monitoring of others (see: Section 3.2.4) may be mitigated by wearable monitors or user control over the system, suggesting that systems must be designed so that monitoring can be temporarily suspended at the user’s request. Such a feature allows the user to maintain personal relationships with individuals not wishing to be monitored. **DC2** and **DP1** believed that some form of consent should be sought from visitors to monitored environments if inadvertent data collection is a possibility. Even if the potential for inadvertent monitoring is eliminated in PHM systems capable of distinguishing between the user and visitors, **DP1** felt the mere presence of the monitoring system may still make visitors uncomfortable.

9.3.3.3 Identity of Data Custodians

Control can also be conceptualised in relation to data sharing. In this context control can refer to choosing which clinicians and institutions receive PHM data, and what type or amount of data is transmitted. The professional role of custodians involved in handling and processing PHM data emerged as an important concern. Four patients indicated that the identity of data

custodians must be known before PHM will be adopted. Medical professionals were overwhelmingly accepted as data custodians, with those in the patient's existing care team preferred. Acceptability was linked to medical training to ensure data custodians possess the necessary expertise to assess the health of the user:

DP4: "As long as I know it's only going to medically trained people or similar, people who maybe they're not doctors but they've got the ability to sort out the data and everything else."

Acceptable data custodians beyond the care team were variable across the patient sample. When asked, most participants found sharing anonymised data with researchers and NHS administrators for secondary uses acceptable. Private companies were rejected by all participants asked about the ethical acceptability of transmitting data beyond NHS institutions. **HP4**, **DC2** and **DP3** expressed a concern that private companies given identifiable data would attempt to "fix" medical problems faced by patients, leading to undesirable advertising focused on a patient's personal medical history. Similar concerns were not raised about the handling of PHM data by the NHS, suggesting broad public health measures (which also seek to persuade patients to some degree) are more acceptable than targeted advertising. Alternatively, this lack of concern may be explained by the NHS operating on a 'not for profit' basis, whereas private companies and medical institutions typically operate 'for profit'.

9.3.4 Informal Care Relationships and Burdens of Monitoring

Another theme in the data which reveals limitations of the conceptual framework relates to the ethical implications of PHM for informal carers. Dementia carers involved in the study spoke about the burdens faced in adapting to an informal care role and the potential for PHM to support carers or create new burdens. Becoming an informal carer for a person with dementia requires coming to understand the disease and its effects on a loved one, and the new burdens which must be shouldered in shifting roles from, for example, 'wife' or 'sister' to 'carer' (cf. Palm 2011). The introduction of monitoring systems was thought to exacerbate changes to the relationship between carer and patient which started when the need for care first arose—**DC1** saw the technology as "just another symbol" of the changes already occurring in the relationship, which can be understood as an example of medicalisation which may increase if dependent patients are increasingly kept at home supported by health monitoring (see: Sections 5.2 and 8.2.2.1.1):

DC1: “The other thing that does concern me a little bit is that, I know the meaning is to keep people with dementia in their home as long as possible, in the community as long as possible, but I can't help feeling that, you know, the home almost becomes hospitalised, you know, when you start getting these, all of these different aids and adaptations to your home... it's something that (pause) affects not just the person being cared for, but the carer, you have to adapt to that, you have to adapt to the fact that your home is becoming medicalised.”

Adjusting to a carer role was described as a “slow change.” **DC2** and **DC3** compared caring to taking care of a child, needing to anticipate dangerous or irresponsible things the patient may do as the disease progresses. Three of the carers interviewed emphasised the difficulties of coping with the burdens of caring, while identifying a need for greater support for informal carers (e.g. respite services, professional care) from social services or medical institutions, perhaps through PHM.

Informal carers make significant social, economic and emotional sacrifices to provide care, such as moving in with an elderly parent to provide care or adjusting work and social schedules to the needs of the patient (cf. Palm 2011):

DC1: “I feel that there's a tremendous loss of identity once you become a carer, you know particularly if you had to give up a job to do it. And with the social isolation that often comes with being a carer. Anything that you feel that robs you of your identity that makes you a number I don't know, I don't like the thought of someone being able to collect data on me.”

PHM is seen here as contributing to the loss of identity central to caring. A related problem to which PHM contributes is the medicalisation of the home through installation of assistive devices for the patient. These types of burdens show that PHM installed to help a dependent patient invariably has implications for informal carers as well.

9.3.4.1 *Lack of Choice for Carers*

Carers reported feeling pressure to accept ethical burdens of monitoring for the sake of the patient. According to three carer participants, informal carers cannot seriously consider rejecting PHM if monitoring is in the best interests of the patient, suggesting that the burdens of monitoring for the carer may become a new unavoidable aspect of informal carer relationships:

DC2: “If it helps the person concerned, then I suppose we [carers] would go along with it, with these things. And if it just keeps them out, people, old people, all the people out of these awful homes, then yes, I suppose, yes, we would go along with anything that would help.”

DC3: “But it’s, it’s, it’s like having a spy in the house, you know, that’s where the stumbling block is, isn’t it?... I’d just feel as though I was just spying. Rather than actually making sure she was all right, I would feel as though I was spying on her...I would get over it. Because I would realise that this is necessary and it has to get done... I suppose you grow up with it: you don’t spy on people. It’s not the right thing to do. And I suppose that’s what’s gotten into my mind and I’ve got to get past that. For my mother’s safety, and for my peace of mind.”

To extend the lack of choice to the conceptual framework, accepting monitoring for the sake of the patient and putting asides one’s interests in privacy or a home free from colonisation may become a de facto moral obligation of informal care. As this suggests the ethical implications accepted along with monitoring are not simplistic; PHM may benefit the carer and patient, while simultaneously violating the carer’s norms of acceptable behaviour (e.g. not ‘spying’ on others) or imposing new burdens such a loss of privacy in the home. The burdens of monitoring may also be tangible; **DC1** compared the installation of monitoring to installing medical devices in the home which help keep the patient safe, but medicalise the home:

DC1: “It’s like, you know, if you have to put a stair gate in. (pause) I’m not saying it’s wrong to do that, I’m just saying, it’s something that affects not just the person being cared for, but the carer, you have to adapt to that, you have to adapt to the fact that your home is becoming medicalised.”

Although the default position in this ethical tradeoff appears to favour the interests of the patient over the carer, this in itself does not justify the burdens placed on the carer— alternative solutions which reduce the burdens may be possible, including alternative methods of supporting the carer and patient (see: Section 3.3.2). In England carers are implicitly expected to increasingly shoulder the burdens of care in the community (cf. Palm 2011; Section 5.4.1.2), which may include monitoring for the sake of the patient.

9.3.4.2 Evaluations of Informal Care

One of the perceived burdens accompanying PHM was the potential for external evaluations of the quality of informal care, against which **DC1** was very critical:

DC1: “It would be fine as long I as I didn’t feel people were looking at it and making judgments...home is a very private part of your life, isn’t it? It’s the one place where, you know, uh, you can escape from the world. I suppose, what I think might be an issue would be if, if people felt that this data was being used to judge how good a job they were doing with caring for someone. Like, you know, if it was picking up all the person’s stress levels or high anxiety levels, they obviously can’t care for this person properly. Or, you know, this, this person’s wandering about the house and the carer’s

still in bed...It smacks of Big Brother to me. It smacks of people making judgments without having the full picture, without knowing the individual who's doing the caring. And so, yeah, I don't like the fact that this data could be used to make a judgment about how effective someone is as a carer."

While recognising the need to protect patients from inadequate care, she felt using PHM in this way would result in inconclusive or decontextualised evaluations because the context in which the care is provided would not be transmitted via monitoring. The prospect of data being out of her control was seen as a problem, meaning she worried that data custodians would draw overly critical conclusions of her ability to care based on an incomplete picture of the care environment, perhaps without her being aware such decisions are being made by data custodians. **DC1** later described this possibility, should it occur, as a "gross invasion of [her] privacy." Although this can be described as an example of decontextualisation, this concept has not yet been applied in the reviewed literature (see: Chapter 3) to informal care relationships or a professional medical institution evaluating the care provided by an informal carer. The possibility of 'decontextualisation in informal care' can therefore be considered a new dimension of the concept, and should be given attention in future research, development, deployment and governance of PHM in informal care situations.

9.4 Discussion

As the primary purpose of the study was to test and refine the conceptual framework, the themes discussed above need to be connected to the explanatory power and limitations of the framework in more detail. Before addressing the framework directly, it is worth considering the impact of the findings of the empirical study on the linkages between ethical themes identified in the reviewed literature above (see: Section 3.4.2). Connections identified as important or absent from the map according to the findings of the study can help identify potential limitations of the framework.

9.4.1 Cognitive Map

The results of the empirical study confirm the importance of certain concepts and connections in the cognitive map of ethical linkages (see: Figure 9.4), originally created through analysis of the reviewed literature above (see: Section 3.4.2), while also requiring certain revisions. In terms of areas confirmed in the findings of the study, the importance of autonomy was reaffirmed by patients emphasising the need for feedback to see benefits and feel in control of PHM (see: Section 9.3.1.1). The importance of links between surveillance, medicalisation, obtrusiveness and visibility was reaffirmed, as participants expressed concerns regarding the

potential for behaviour modification if systems were perceived as 'spying' on them, or particularly visible or physically/psychologically obtrusive (see: Section 9.3.2). The power given to carers, clinicians and institutions was reaffirmed by concerns over social sorting when PHM data is shared with these stakeholders, confirming the link between data sharing, power and autonomy (see: Section 9.3.2.2).

In considering the concepts and links mirrored in the findings of the study, it is worth remembering that the data was analysed to test the explanatory power and limitations of the framework, meaning known concepts seen as existing beyond the framework (such as privacy) may have been important to participants, but not given much attention in the analysis. This potential limitation was an inevitable outcome of focusing on the conceptual framework, while seeking to identify unforeseen concepts or issues beyond those seen in the reviewed literature. These 'outlying' findings suggested the need for revisions to the map and framework alike.

In terms of revisions, the power of informal carers was separated from that of clinicians and institutions to draw attention to the predicted growth in importance of informal carers in PHM-mediated relationships with dependent users, and to identify informal carers as non-professional stakeholders in medical relationships. A duplex connection was established between carers and clinicians/institutions to reflect that as one takes on a greater role in the medical relationship reflected in the sharing of PHM data, the role of the other is likely to reduce, even if only in terms of the relative proportion of care provided to the patient. Data sharing was linked to feedback to represent the opportunities for clinicians and institutions to provide feedback to patients when data is shared among providers of medical care. Feedback contributes to autonomy and control both because it was perceived as empowering the patient with greater access to information about their health, creating opportunities for behaviour modification, but also because feedback and access to PHM data was perceived as keeping clinicians honest (see: Section 9.3.3.1). Control was added to autonomy to reflect its importance in the data (see: Section 9.3.3), despite similarities between the concepts.

An explanation of the relationship between the cognitive map and conceptual framework has been offered above (see: Section 4.1). The original map created in Chapter 3 (see: Figure 3.2) was created solely from the perspective of colonization of the lifeworld, which is related to medicalization. This updated map (Figure 9.4) reflects new links and concerns identified

through consideration of the conceptual framework, and the concerns raised by participants in the empirical study. The map, as a tool built from the framework, is intended to assist in application-specific analysis in the future by translating the conceptual framework into a 'mid-level' tool more easily applied to the analysis of applications in specific contexts of use. For example, it may be useful to doctors, potential users, developers, or policy-makers to understand how different implications of PHM for medical care connect to or contribute to each other, thereby helping explain the implications of a specific application in a specific context.

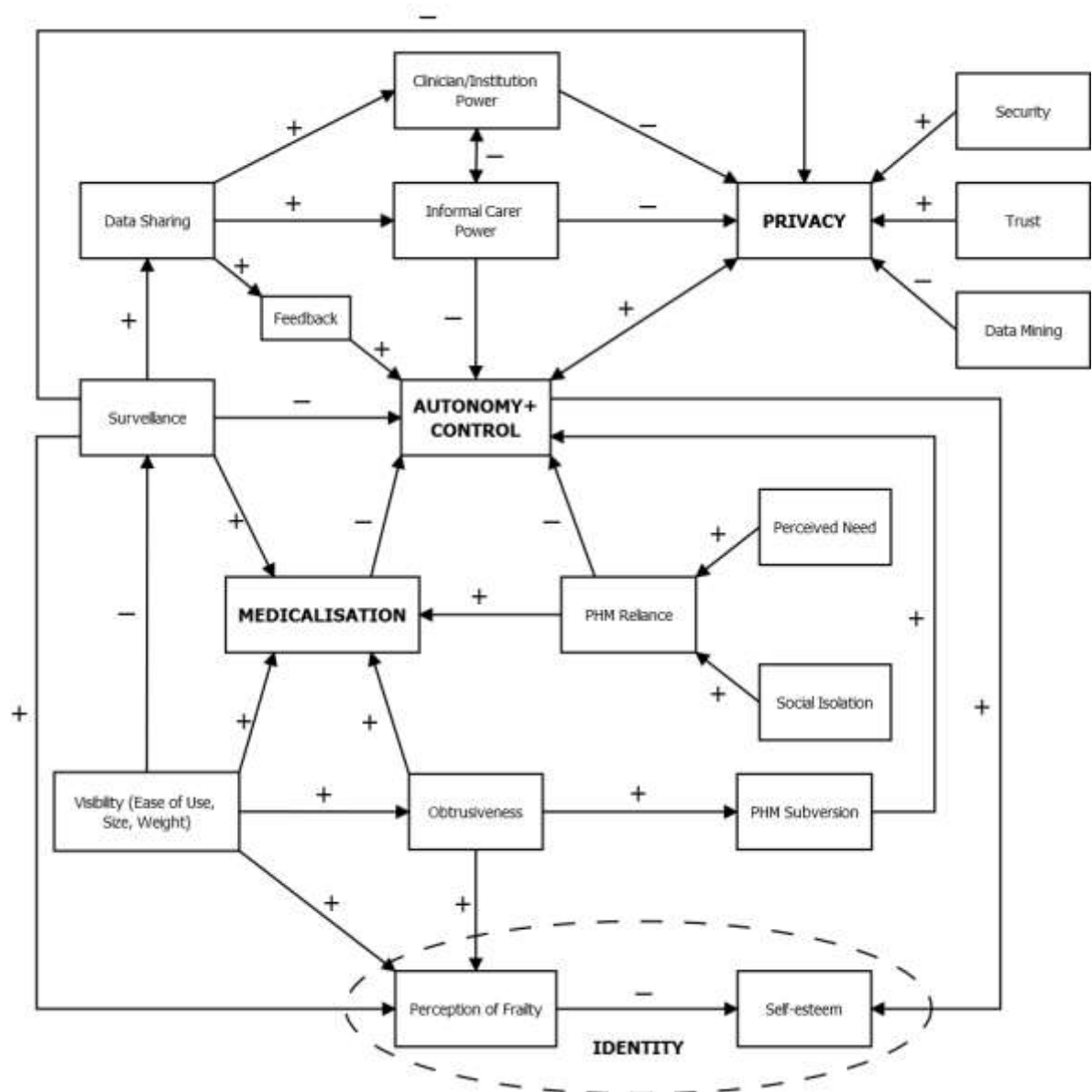


Figure 9.4 - Revised Cognitive Map of Linkages between Ethical Themes from the Perspective of the User

9.4.2 Explanatory Power of the Framework

Of the claims encountered in the study concerning aspects of relationships, a majority were explicable within the conceptual framework (see: Sections 9.3.1 and 9.3.2), suggesting the framework is a helpful theoretical tool for understanding the moral potential of PHM. Concerning the motivations behind diffusion of PHM (see: Section 9.3.1), a gap exists between the motivations for using PHM perceived by patients and professionals. For patients, PHM is seen as a tool to improve clinical care—the purpose of monitoring is to improve the patient’s health and medical care. This finding reaffirms the importance of virtuous medical practice, in particular concerning the virtues of fidelity to trust and beneficence (see: Section 4.3.3). While professionals recognise the potential to improve medical care, the primary motivation evident in the responses of care commissioners, seen also in DH strategy (see: Section 5.2), is to meet efficiency goals, for example reducing the length of hospital visits for COPD patients (cf. Steventon et al. 2012) or consumption of residential care resources. In discussing the possibility of PHM with patients, clinicians may have a duty to be honest about the motivations behind support for PHM beyond any potential clinical benefits. Without such honesty informed consent cannot be achieved, and practice may fail to be virtuous.

In the language of cost-efficiency the possibility for PHM to reduce the quality of care is evident, meaning reductions in quality may be justifiable by increases in quantity. Put another way, reduced costs may justify reduced quality at sufficient savings levels. This is not to suggest the care commissioners involved in the study are guided by utilitarian calculations alone, but rather that the potential for efficiency gains is a chief motivator behind institutional support for PHM.

The conceptual framework helps explain the potential problems caused by this gap; patients may be unaware of qualitative changes in the medical care they receive motivated by efficiency, assuming instead that PHM, as a new medical technology, must be better than existing practice in terms of the quality of care provided. The importance of efficiency as motivating PHM diffusion can be conceptualised as institutional values colonising the internal goods of medicine, which while not unprecedented, remains ethically problematic if PHM inhibits virtuous practice in the healing relationship, as suggested above (see: Section 4.3.4). The risk presented here is that patients may be ‘blissfully unaware’ of the analysis and

categorisation made possible by PHM, conceived as a surveillance technology, while being reassured of the quality of care provided by PHM by institutional support for the technology. Users may not be equipped to understand the ethical implications of PHM in this regard, defaulting instead to a position of trusting institutions and clinicians to have their best interests in mind in providing care (see: Section 4.3.2.1).

Concerning the prospects of feedback (see: Section 9.3.1.1), the conceptual framework helps explain why PHM creates ethically problematic opportunities for health obsession or uninformed decision-making among users. In existing healing relationships patients access the expertise of physicians in clinical encounters, during which the physiology and concerns of the patient are assessed and, if necessary, diagnosed. PHM creates new opportunities for medical ICT to analyse health data and feed results back to the user without the oversight of a clinician. In contrast to ideal clinical encounters, information received in this way may be misunderstood by users, potentially leading to decisions to alter behaviour or interventions ‘uninformed’ by the expertise of a clinician. If clinicians are closely involved with PHM, meaning systems are restricted from providing feedback to users without clinical oversight as recommended by care commissioners in the study (see: Section 9.3.1), a conflict is created between institutional and user interests. The need for control realised through unrestricted access to personal data means that systems cannot be simultaneously restricted and open, making an ‘ideal’ deployment respecting the interests of both parties impossible; a balance must be struck between the conflicting interests in patient safety and patient control. This type of balance is a new problem for the healing relationship based on PHM acting as a mediator capable of providing ‘medical expertise’, or at least personal health information, directly to the patient.

The framework also helps in understanding the implications of information overload. To ‘close the loop’ concerning the increased work of assessing PHM data, a member of the care team will need to analyse incoming PHM data and contact the patient with feedback and recommendations, which creates a significant amount of additional work. If PHM is to be used on a large scale this problem must be addressed. A possible solution is for PHM to undertake some aspect of data analysis, perhaps presenting simplified data or reports to clinicians rather than raw data. However, this possibility raises questions over the algorithms responsible for analysis—in effect clinical judgments would be made in proxy by the developers (of PHM systems and analysis procedures) who program the system to view a set of data in a certain way, for example classifying a particular physiological reading as an emergency requiring

immediate attention from health professionals. Furthermore, institutions which offer feedback directly from PHM systems risk liability for incorrect or confusing information causing medical problems for patients. Another possibility is that PHM systems are designed to provide information and feedback directly to the users who assume a more prominent role in their care, using PHM to support self-care. In both cases the removal of the physician to some degree from the healing relationship suggests ethical problems may arise as new relationships are formed between users, systems and non-clinical service providers; for instance, low quality feedback or data analysis based on outdated clinical knowledge may be provided to patients. At the same time the role of the physician in the healing relationship changes, inhibiting realisation of practice internal goods through virtuous behaviour when contact with the patient is reduced.

Decontextualisation was identified as a related problem to information overload. To combat decontextualisation in medical care, access to the medical record is needed by stakeholders involved in the analysis of PHM data or providing feedback to users (see: Section 9.3.1.3). PHM therefore necessitates patients consenting to broader access to their personal medical record. Even if access is granted, it is unclear how access to the patient's complete medical record can account for social effects on health, for example if a patient's blood pressure is temporarily elevated because he forgot to take his tablets or is experiencing stress at work. The conceptual framework helps explain the ethical implications of this proposed solution to decontextualisation; a risk is created of losing the socially embodied patient in PHM-mediated care if access to medical records is seen as a sufficient remedy, reducing the importance of social, emotional and psychological aspects of health. These aspects of health also retain reduced importance in care commissioning (see: Section 9.3.1.4), which within the conceptual framework can be seen as an example of institutional values, or those outcomes of PHM which can be 'costed', inhibiting the realisation of practice internal goods related to non-quantifiable aspects of medical care.

Concerning ethical tradeoffs 'forced' onto users through PHM adoption (see: Section 9.3.1.5), the conceptual framework suggests that tradeoffs are created by the pursuit of institutional values within medicine, rather than internal goods of the practice. In seeking efficiency through PHM new ethical issues, such as those identified above, are created, meaning users consent to a 'bargain' in which they must accommodate PHM to receive its benefits (e.g. perceived improvements in the quality of care). Institutional values are accepted into the

patient's lifeworld through such bargains, although this form of colonisation is qualitatively different than that accepted in receiving traditional face-to-face care because of the constant presence of the monitor, and the medical concerns it represents, in the lifeworld.

9.4.2.1 Surveillance

Claims regarding surveillance were entirely comprehensible through the theories of surveillance considered above (see: Section 4.4). As seen in academic discourse (e.g. Welsh et al. 2003; Percival & Hanson 2006) 'Big Brother' proved a common metaphor for surveillance despite its inaccuracies concerning the infrastructure through which PHM is adopted. For care commissioners the potential for social sorting explored above proved relevant to explaining how categorisation of patients on the basis of PHM data may affect the patient's self-identity and treatment at the hands of medical institutions and health professionals (see: Section 9.3.2.2).

It is notable that PHM was only spoken of as surveillance by patients. Among professionals, only one dementia service officer referred to PHM as surveillance, describing video monitoring as "like Big Brother, an invasion of privacy" (**DM1**). The fact that patients speak of PHM as a type of surveillance, which when described in terms of 'Big Brother' takes on a distinctly negative connotation, suggests that a gap exists between how patients and health professionals view the moral potential of PHM. For patients, PHM as 'Big Brother' is a tool which allows monitoring of patients and their behaviours, creating an initial perception of being watched by 'others'. For health professionals, PHM is yet another tool to assist in providing medical care, creating new means of data collection, analysis, contact and feedback with patients.

Although PHM is not obviously sinister in an Orwellian sense, problems can occur when patients perceive themselves as being watched through PHM. Behaviour modification was linked to the mere presence of a monitor in the home or on the body, which serves to remind the user of their condition and the potential of a third party 'watching' them through the monitor (see: Section 9.3.2.1). Modification can be thought of as a form of control or bio-power exercised by monitoring systems and their custodians over users. As behaviours are changed based solely on the *perception* of being watched, it is irrelevant whether actions are taken in response to monitoring data. Although behaviour modification can be related to issues of stigma and surveillance, an account of control linked to ideas of autonomy or

freedom of choice, each of which may be inhibited when users behave differently based on the perception of being watched, is necessary to conceive of behaviour modification as an ethical issue. This limitation of the conceptual framework suggests how its explanatory power may be improved through minor refinements.

9.4.3 Limitations of the Framework

The link between control and autonomy seen in the study (see: Section 9.3.3), through which control enhances the user's ability to define and pursue personal values and projects free from external interference, suggests that the conceptual framework could be improved through the inclusion of a theoretical account of autonomy and its role in relationships mediated by PHM. Such improvements will complement the virtue-based approach to medical relationships by explaining how power is exercised. Understood in these terms, the need for control reveals norms of acceptable PHM-mediated relationships, with each aspect of control mentioned helping to explain the expectations of patients in relationships with clinicians and institutions mediated by PHM.

9.4.3.1 Control and Autonomy

The prevalence of control in the claims of participants in the study exposes a limitation of the conceptual framework. An appropriate concept or theoretical framework to 'make sense of' the desire for control is missing, suggesting the need for further refinement. One possible way forward, albeit a preliminary one at this stage, is to connect the desire for control with autonomy.

Autonomy is an exceedingly broad concept referring to some aspect of human character which is self-determining. Among different approaches to philosophy there are innumerable specifications of the concept (Dworkin 1988, p.9). Autonomy can be defined as "self-governance, that is, the ability to construct one's own goals and values, and to have the freedom to make one's decisions and perform actions based on these decisions" (Brey 2005, p.160). A fundamental link exists between control and autonomy at a conceptual level, as both relate to freedom of choice or action on some level.

Adding autonomy or a related concept to the framework to make sense of the desire of users for 'control' is not a simple task, as any theoretical position must be reconciled with the other theories present in the framework. The purpose of focusing on autonomy as a candidate is not to champion any particular conception of autonomy and explore its implications for the

framework; to do without first assessing the nature and importance of control in other contexts of PHM usage would be premature. Without the benefit of such research, the best that can be accomplished is initial speculation as to the role autonomy could play within the framework as a way to explain the desire for control over PHM and medical relationships.

9.4.3.1.1 Control and Relationships

As an example of how control relates to autonomy as such, PHM can be seen as undermining the patient's ability to decide what personal information to share about oneself. Control over information is traditionally initially strong in the healing relationship, during which the patient chooses how far to 'expose' his body and history to the physician. Autonomy can be expressed through feeling 'in control' of one's health or medical conditions, or management of (information about) health or conditions.

As used by participants, control reflected a desire for greater influence over PHM systems, extending to being able to limit the movement of data about the user. Although control reflects a desire for greater influence in medical relationships to some degree, this should not be taken as equivalent to a desire for self-care or self-responsibility, such as that seen in England (see: Chapter 5). Rather, through its connection with autonomy, control can be understood as a desire to maintain some degree of freedom in the lifeworld and choices in medical relationships, while not necessarily reflecting a desire to take greater responsibility for one's healthcare.

The desire to control data flows seen in the study can also be understood in terms of self-responsibility for health care (see: Section 9.3.3). Data privacy (see: Section 3.2.1.1) can be connected to control and autonomy in the sense that the user can restrict the power of others by limiting the availability or movement of personal data (cf. Nissenbaum 2004, 131). In relation to PHM, the restriction of information implies that the user's future actions are comparatively less restricted by the desires of third parties, such as carers or clinicians, who would otherwise act on the information. Autonomy could therefore have dire consequences for the patient, who retains independence in actions at the cost of third party interventions designed to benefit his health.

9.4.3.1.2 Control and Virtuous Practice

It can be argued that patients exercising greater control in PHM-mediated relationships will act as a counterbalance to a potential loss of 'good' medical practice, or a healing relationship in

which the internal goods of medicine are realised, caused by PHM (see: Section 4.3.4). The ideal of 'self-responsibility' for health under the self-care model (see: Section 5.4.1.2) can be taken to mean that patients must exercise greater control in the relationship to maintain adequate medical care when faced with the prospect of reduced contact with physicians and other health professionals morally obligated to pursue the internal goods of medicine. However, it is doubtful that all users of PHM will understand the greater responsibility that accompanies control over PHM and its data.

While control can lead to greater autonomy in PHM-mediated relationships for patients, it is not a guarantee of 'good' medical care, when 'good' care is of a sort which can only be provided, or at least identified, by practitioners familiar with (methods to achieve) the internal goods of medicine as a practice (see: Section 4.3.1). It is therefore ethically problematic to assume PHM, users, service providers, data custodians or other medical stakeholders lacking the experience necessary to grasp the internal goods of medicine (see: Sections 4.3.1.1 and 4.3.2) can replace the loss of opportunities for virtuous practice, where such loss is brought about by providing care remotely to decontextualised patients amenable to social sorting and physiological categorisation. That patients may need to exercise greater control over the healing relationship, understood as an expression of autonomy, means that some of the responsibility for 'good' medical care is passed to patients.

9.4.3.2 Informal Care and the Conceptual Framework

Beyond the need for patient control in PHM-mediated relationships, limitations can be seen in the framework's treatment of informal medical relationships, such as those engaged in by informal dementia carers. Of the 'patient' participants in the study, dementia carers provided the richest data in terms of understanding the implications of PHM for personal and medical relationships. This finding may be explained by the involvement of informal carers in existing relationships which blur the boundary between 'personal' and 'medical', as well as their insight into the needs of the patient in terms of care and for support for the carer in coping with the burdens of care.

In discussing the ends of medicine in the conceptual framework (see: Section 4.3.2), insufficient attention was paid to alternative medical relationships occurring between patients and non-professionals such as informal carers, charity workers or service providers. Informal carers are not bound by the same moral obligations as clinicians or professional carers (cf.

Palm 2011), in part because entering into informal care is not always a freely made choice equivalent to joining the medical profession. The framework could be improved by addressing the unique shift from personal to medical relationship which characterises the move to informal care, seen for example in the perceived impossibility of rejecting PHM which is beneficial for the patient, itself requiring an account of autonomy. Without such an account it is unclear how the virtues and internal goods of medicine, best seen through the healing relationship, can be applied outside of the patient-clinician-payer model. As care is increasingly shifted to the community and patients in England, non-professional medical relationships are likely to become increasingly important in the delivery of medical care.

While an account of the moral obligations of family members and friends to provide medical care goes beyond the scope of this thesis, on the surface parts of the account of the healing relationship offered above (see: Section 4.3.2.1) appear to transfer cleanly to informal care relationships. The account would require modification with regard to patients seeking out informal carers not for medical expertise but for support in activities they can no longer achieve alone. Additionally, it is not clear that informal carers must always prioritise the interests of the patient above their own, suggesting a revised account of the need for self-effacement among informal carers. Despite these initial limitations, the patient's position in the healing relationship does not obviously change, characterised as it is by vulnerability, the necessity of trust, and the desire to return to a state of equilibrium.

9.5 Conclusion

The empirical study demonstrated the explanatory power of the conceptual framework. Limitations and areas in need of refinement were identified concerning patient control and autonomy in PHM-mediated relationships, and the ethical implications of PHM for informal carers not bound by the moral obligations of medicine, or versed in its internal goods. Although initial amendments have been offered, the process of refining the framework must continue in response to future developments in PHM and strategic support.

The empirical study fulfilled the requirements of the hermeneutic methodology for empirical ethics analysis under conditions of uncertainty described above (see: Chapters 6 and 7). At the beginning of the project the researcher created an account of his prejudices (see: Chapters 1 to 4). Modifications to these prejudices and the developing understanding of the ethical implications of PHM for relationships can be seen throughout the project, up to and including

the discussion of results in this chapter. The interviews were modelled on hermeneutic dialogue, in which a 'fusion of horizons' (see: Section 6.1.3.2.1) was achieved through dialogue between the researcher and participants. Data analysis consisted of a subsequent dialogue between the empirical texts and the researcher, in which the researcher exercised reflexivity to identify and understand his prejudices in developing understanding of the phenomenon (see: Section 6.1.3.2.2). The revised understanding of the phenomenon can be seen in the conceptual framework and the interpretation of empirical data. The fusion of horizons continued throughout the subsequent dialogue with the texts, seen in the developing understanding of the ethical implications of PHM for personal and medical relationships, and in testing and revising the framework.

The purpose of the empirical study was to expand the researcher's understanding by identifying local concerns according to different potential users. Activating this feedback loop which expands the range of known ethical concerns is important to improve the quality of ethical discourse and understand potential limitations of the conceptual framework. The contributions of potential users of PHM in the empirical study, and their ability to participate in ethical analysis through hermeneutic dialogue, demonstrates that ethical discourses need to include both experts and laypeople, who can offer theoretical and local perspectives respectively, to achieve comprehensive analysis in which both types of issues are identified and specified. In keeping with the hermeneutic paradigm, the understanding of the ethical implications of PHM developed so far is incomplete and open to alternative perspectives and evidence in the future. In recognition of this, before concluding the project consideration must be given in Chapter 10 to whether the discourse established here sufficiently answered the research questions posed, and how PHM ethics discourse can be advanced in the future.

10 Chapter 10: The Moral Potential of PHM

10.1 Introduction

Throughout the research reported in this thesis, a range of methods have been used to investigate the moral potential of PHM, or its potential to 'cause' ethical problems in the future. The empirical study described above was built upon a systematic review of academic literature and theoretical analysis responding to perceived gaps in the discourse. Each of these methods was meant to explore the moral potential of PHM to change how patients experience personal and medical relationships with others when such relationships are mediated by PHM.

The research was designed in response to perceived procedural and substantive gaps in existing PHM ethics research, expressed through research questions throughout the project. To evaluate the outcomes and credibility of the project, it is necessary to consider how each research question, built upon a perceived gap in the discourse, was answered through the research activities described here. In answering the questions posed in the first half of the thesis (see: Section 5.6), the research made a significant contribution to explaining the moral potential of PHM.

10.2 Addressing the Research Questions

The project answered four research questions posed in response to perceived gaps in academic discourse and prior research addressing ethical implications of PHM:

- 1. How can PHM be defined?**
- 2. How can PHM be categorised to link potential ethical implications to specific emerging applications?**
- 3. What ethical considerations will arise when PHM is introduced into relationships between patients, clinicians and medical paying organisations?**
- 4. What methodology is capable of capturing and incorporating the moral beliefs of potential users of an emerging medical technology (such as PHM) into ethical analysis?**

The first two questions were addressed through review of academic research discussing ethical aspects of PHM (see: Chapter 2). PHM was defined as any electronic device or system with the capability to collect, store and transmit data about a health-related aspect of an identified

user's life outside a hospital or similar medical environment (see: Section 2.2). A categorisation of PHM was built upon the location of sensors to help identify connections between technological characteristics and ethical implications (see: Section 2.3). The categorisation is complementary to the taxonomy developed in PHM-Ethics (see: Section 1.2.1), which in addition to location also categorises PHM according to field of application and technological features.

Following on from a gap identified during the literature review, the third question was answered through the conceptual framework which is the main contribution of the research project. The conceptual framework was initially constructed from theoretical perspectives concerning colonisation of the lifeworld, virtue ethics and surveillance theory. As the gap in the discourse concerned relationships between lay persons and experts, or patients, clinicians and institutions, a need was identified to test the framework's ability to make sense of the perspectives of potential users of PHM. An empirical study was conducted in response to this need, through which the framework was refined.

To design an appropriate empirical study and to answer the fourth research question, a methodology capable of combining empirical and theoretical perspectives in ethical analysis under conditions of uncertainty was developed (see: Chapters 6 and 7). The methodology was developed within the philosophical paradigm of hermeneutics and supported by an epistemic framework based in discourse ethics, which responded to the epistemic challenges presented by uncertainty. An approach to 'translation', a concept originally developed but not subsequently unpacked by Habermas in response to the need to include religious claims in secular political discourse (see: Section 7.3.2.3), was developed to distinguish between uncertain and legitimate components in normative claims encountered in the study.

10.3 Contributions of the Research

In providing answers to the research questions the research project has made a conceptual contribution to PHM ethics discourse, a methodological contribution to empirical ethics, and a methodological/epistemological contribution to the ethical assessment of emerging technologies. As an emerging technology, PHM exists in a 'conceptual vacuum' (see: Section 3.3.6). PHM enables tracking the health and behaviours of users, creating opportunities for secondary uses of unprecedented levels of personalised health data. Intended or not, it

creates opportunities for the fulfilment of medical (monitoring) needs by technological applications, rather than human involvement.

The primary contribution of the research project to conceptual understanding of the ethical implications of PHM was the creation of the conceptual framework, which helps explain the moral potential of PHM as a group of technological applications with similar technological characteristics and uses. The framework is novel in the sense that it connects and explores theoretical perspectives not considered in PHM ethics discourse (see: Chapters 3 and 4). Surveillance theory was connected to Habermas' concept of 'colonisation of the lifeworld', and used as a way to understand how PHM mediates medical relationships and introduces institutional values into the patient's lifeworld and medical practice. MacIntyre's virtue ethics was then applied to show how colonisation through PHM as a mediator undermines the practice-internal norms of medicine.

These three theoretical perspectives form a compatible and novel conceptual framework in which specific PHM applications and uses can be evaluated in future ethical discourses (see: Section 7.3.2.1). Each theory helps identify, explain and connect ethical implications beyond those currently considered in academic discourse (see: Section 3.3.6). The framework provides a theoretical lens through which the implications of removing or replacing clinicians and carers with monitoring technologies can be understood, creating pathways or new relationships between patients, institutions and service providers. The creation of such a framework also responds to some degree to the need for context-specific ethical analysis of future PHM applications, identified by both research projects framing this thesis in relation to a lack of context-sensitivity in governance (see: Section 1.2.5).

A secondary contribution of the project is a novel methodology for empirical ethics analysis, and a supporting epistemological framework for empirical ethics assessment of emerging technologies. The methodology can be viewed as a continuation of the empirical ethics movement (see: Section 7.2) which recommends combining empirical data and ethical theory in ethical analysis. It is novel because it is supported by an epistemological framework explaining how empirical ethics analysis can be conducted under conditions of uncertainty, or concerning future states. While the methodology is built around analysis of emerging technologies, the epistemic justification for taking uncertain claims seriously in discourse, based on Habermas' concept of translation, may be a valuable contribution to the

epistemology of other forms of proactive ethical analysis or governance such as Technology Assessment.

The categorisation of PHM (see: Section 2.3.2) which complements the PHM-Ethics taxonomy (see: Figure 10.6) is intended to be used alongside the conceptual framework in future discourses. The combination of the two creates a hierarchy along which ethical implications are inherited. Increasingly complex systems can be mapped on the hierarchy, identifying applicable implications associated with simpler systems. The categorisation can be used to map all types of ethical implications (see: Chapter 3), not only those associated with relationships as understood through the conceptual framework (See: Section 3.4 and Chapter 4).

10.4 Recommendations

Although the conceptual framework was developed primarily as a tool to enhance future context-specific discourses concerning ethical implications of PHM, it can be applied in the present to recommend anticipatory actions among care commissioners, clinicians and institutions faced with the prospect of deployment of PHM in England. The potential for PHM to form a pathway between patients and medical institutions, as well as patients and industry, suggests that the expertise of physicians in recognising and working towards the internal goods of medicine are lost to some degree in the healing relationship (see: Section 4.3.2.1). Stakeholders responsible for deciding how, when and where PHM will be deployed, how its data will be passed on and the purposes for which it will be used, must recognise and respond to this loss of 'expertise of the virtues'. While uncertainty prevails over the future course of PHM it is practically impossible to put this loss into clinical or practical terms for outcomes which primarily affect the patient, but other stakeholders as well. However, if the virtues are recognised as inherently valuable in the sense that they are conducive to the goods of a practice, and if it is recognised that opportunities for virtuous medical behaviour are lost by the 'exit' of the clinician from the healing relationship mediated by PHM, then we have established a position from which to ethically assess future deployments of the technology as more or less ethically acceptable.

From a practical perspective, stakeholders responsible for deployment should strive to include clinicians in PHM mediated relationships as far as possible. Clinician involvement can include analysing PHM data, providing feedback and follow-up to patients, answering questions and

concerns, and as far as possible emulating the face-to-face clinical encounter through remote monitoring. Clinicians or other health professionals may also be required to train patients on the operation of PHM applications, as well as obtaining consent and explaining potential implications of monitoring to patients. A primary ethical risk is to view PHM as a technological means to reduce costs or the need for health professionals in medical care, while still providing the same quality of care; the inhibition of virtuous behaviour suggests doing so is impossible because the technology does not replace the lost expertise regarding realisation of the ends of the healing relationship.

Several recommendations were made throughout the research project based on review of academic discourse, theoretical and empirical analyses. The recommendations addressed issues which should be addressed in the deployment, design, analysis and usage of PHM systems, as well as protection mechanisms and research into ethical issues of PHM. Several recommendations addressed issues which should be addressed when choosing how and why to **deploy** PHM:

- The ability of PHM to colonise and medicalise the patient's lifeworld with institutional concerns, increasingly shifting attention to medical concerns and making patient's responsible for medical care in private life, must be recognised and reduced when possible. Practically speaking, PHM should only be deployed when a clear need exists, to avoid 'monitoring for monitoring's sake' (see: Section 3.4).
- The greater responsibility placed onto patients for medical care by some PHM applications, seen as part of the strategic shift towards self-care, self-responsibility and care needs fulfilled by community rather than medical resources, needs to be recognised so sufficient support or compensation is made available to newly burdened individuals (see: Section 5.4). The burdens placed on informal carers by PHM are especially relevant (see: Section 9.3.4).
- In forthcoming DH and NHS strategy and assessments of the clinical and cost efficacy of PHM, the quality of care provided should not be assessed only in utilitarian terms, or according to factors which can be 'costed', such as length of hospital stays or the cost of care per patient (see: Section 5.2). For example, the value of the expertise of health professionals concerning the internal goods of medicine and the virtues necessary to realise them should be recognised as a valuable factor affecting the effectiveness of PHM (see: Section 4.3).
- Ethical issues can be mapped across categories of PHM (see: Section 2.3), which assists in the identification of ethical issues in specific contexts for specific PHM applications

when considering deployment. A taxonomy or categorisation such as the one developed here should be used in designing deployment programmes.

- Ethical tradeoffs in adopting PHM should not be accepted as inevitable ‘costs’ of using the technology; rather, systems and deployment programmes should be designed to address the ethical implications of PHM as far as possible, while still recognising that certain tradeoffs may be inevitable (see: Sections 3.2.3.1 and 3.3.2).

Other recommendations concerned problems that can be addressed through **system design**:

- The potential for PHM to medicalise the lives and spaces of users should be recognised, and reduced where possible by designing systems to reduce physical and psychological obtrusiveness (see: Sections 3.2.4 and 3.2.9).
- The potential for behaviour modification should be reduced by designing systems to monitor users through the least obtrusive means possible (e.g. video data vs. movement data), as well as training users to have realistic expectations regarding the ability of service providers to monitor them through PHM applications (see: Section 9.3.2.1).
- Systems and care plans should be designed to respond in some way to the need for user control over PHM systems as an extension of maintaining power in medical relationships with clinicians and institutions (see: Section 9.3.3).

Still other recommendations addressed issues to be addressed by data custodians or system operators responsible for **analysis and usage of PHM data**:

- Transparency is required regarding the data held by the NHS about PHM users, the identity of data custodians (see: Section 9.3.3.3), the process of defining new categories within PHM-linked databases, as well as the process of matching users to categories (see: Section 4.4.3.1.4).
- The power granted to medical institutions through PHM data to monitor and categorise users according to groupings reflecting institutional or clinical concerns should be recognised by data custodians and clinicians as not reflecting the entirety of the user’s experience. The ‘socially embodied patient’ may be missing from the data representation (see: Section 4.4.3).
- Going forward, the possibility of decontextualisation in monitoring informal care relationships through PHM should be recognised and addressed through alternative methods of gathering contextual data before assessing the performance of carers (see: Section 9.3.4.2).

Two recommendations were made concerning limitations of **protection mechanisms**:

- Tangential health data, such as behavioural data collected by PHM which does not concern a physiological parameter of health, should be recognised as ‘health data’ deserving stringent protections under existing and forthcoming data protection legislation (see: Section 3.3.3.2).
- The difficulties of obtaining informed consent due to the inherent uncertainty of the future should be recognised, meaning systems should be presented to potential users as having uncertain implications (see: Section 3.3.3.1). Practically speaking, a ‘veneer of certainty’ should not be presented by developers and health professionals over the future implications of the technology and its data for users.

Finally, five recommendations targeted issues with existing **research** into the ethical implications of PHM:

- The technical and demographic scope of ethical analysis of PHM should be expanded to address for demographics of potential users largely ignored thus far in the discourse (see: Section 3.3.1).
- In the future a common definition of PHM should be adopted in academic discourse to facilitate ethical analysis of systems with similar technological capacities and potential uses in medical care and lifestyle monitoring. A definition and categorisation of PHM was developed to this end (see: Chapter 2).
- PHM ethics discourse should provide information on the theoretical background informing empirical research or conceptual analysis (see: Section 3.3.6). This recommendation is especially relevant to privacy discourses among developers and security experts, which currently suffers from ‘privacy myopia’, failing to recognise privacy norms as context-specific (see: Section 3.3.4).
- In future discourses concerning surveillance aspects of PHM, the ‘Big Brother’ and panopticon metaphors should be replaced with metaphors which better describe existing PHM deployments and strategy (see: Section 4.4).
- Future ethical assessment of emerging medical technologies, including empirical ethics and Technology Assessment, should acknowledge the epistemic difficulties caused by uncertainty, and work to develop methodologies capable of distinguishing between certain and uncertain components of normative claims about potential futures. Such a method has been recommended above (see: Section 7.3).

All of these recommendations seek to improve future discourses concerning ethical implications of PHM by explaining the moral potential of PHM at different stages of design, deployment, usage and research. In discourses concerned with justifying usage of PHM in a

particular context, the recommendations may change how the effectiveness of PHM is assessed, with the aim of preventing problematic ethical issues from occurring.

10.5 Limitations

Despite the significant contributions and recommendations made by the project, some limitations can be identified. Limitations are seen in relation to a potential lack of context-specific empirical analysis based on the makeup of the study sample, the applicability of results beyond the context of study, and the restrictions created by NRES.

10.5.1 Context-Specificity and the Sample

As hinted at above (see: Section 10.3), the empirical study somewhat lacked context-specificity due to not examining an extant use of PHM. While the study did not look at the implications of any particular PHM application or context in which PHM is currently used, its results were used to refine the conceptual framework which is designed to contribute to future context-specific discourses. On this basis the research was only context-specific in a theoretical sense, while lacking the context-specificity achievable only through examining an extant use of the technology. The lack of a sample of existing users of PHM precluded context-specific ethical assessment with non-experts.

It may be argued that if a sample was recruited with prior experience with PHM, the credibility of the empirical study would have improved because of the link between experiences within a practice and the credibility of normative claims (see: Section 7.2.1). As the study stands, the claims of potential users of PHM have *initial* credibility based on experiences with practices relevant to PHM, such as informal care or chronic illness management. Alternatively, current users can relate normative claims to experiences with the technology, making them more credible than claims based on hypothetical scenarios. Implications concerning relationships actually affected by existing uses of a PHM application could have been identified by current users, providing a credible basis to refine the conceptual framework without the need for translation. As PHM comes to be deployed in England, opportunities to recruit such a sample to a similar study in the future will arise.

A sample of existing users would also increase the comprehensiveness of the study by allowing for a larger sample with similar background experiences. As it stands the study sample was relatively small in the sense that five patients were recruited from each 'disease group', along with two disease specialists, two service officers and three care commissioners. Such diversity

in a relatively small sample increases the difficulty of finding meaningful relationships and themes within the data, if only because the background social and professional experiences of the participants are so diverse. For the exploratory case study method employed a larger sample size would have been ideal, with more participants from each participant group; however, the size had to be limited due to the research being carried out by a single researcher, and involving up to two interviews with each participant.

10.5.1.1 Users of Related Technologies

While it could be argued that a sample of users from pilot studies of related telehealth and telecare technologies (see: Section 5.3.1) could have provided data grounded in practical experience with remote monitoring, the fact that the piloted systems were related to but not examples of PHM limits the weight of this argument. Compared to PHM, piloted systems lacked longitudinal and semi-constant monitoring without active interaction from the user (e.g. answering questions and taking measurements). At best, when compared with the actual sample of patients with a chronic illness, prior users of systems related to PHM could make an equivalent claim to the initial credibility of claims about PHM. Such a claim would be based, from the view of 'moral wisdom' (see: Section 7.2.1), on their having past experiences which inform their claims about PHM. In other words, the 'tangential' experiences of chronic illness management and telehealth/telecare can equally base credibility claims concerning statements made about PHM, as both are related but not equivalent to PHM usage. With regard to PHM, experiences with telehealth/telecare are not self-evidently of greater value in terms of grounding credibility claims than experiences with chronic illness management or other forms of health monitoring (see: Section 8.2.1).

10.5.1.2 Advantages of Potential Users

With that said, recruiting potential users to the study did generate certain advantages; for one, the experiences of the sample were not limited to a single PHM application, covering instead multiple hypothetical systems based on current development. This approach is well-suited to testing and refining a conceptual framework built upon theoretical perspectives not encountered in existing PHM ethics discourse because it is conducive to identifying unforeseen ethical implications relevant to the technology, but not necessarily a particular application. For example, interviewing users of a blood pressure wrist watch could reveal implications relating to behaviour monitoring or pressure to adhere to recommended treatments, but say

nothing of the implications of environmental monitoring with the potential for inadvertent monitoring of non-users.

10.5.2 Context of Study

Another potential limitation of the study is that the findings of the empirical study may be limited in applicability to England, based on the existence of a national health service with common resources and structure across the country. It is unclear whether the results of the empirical study can be applied further afield than England or even the East Midlands (see: Section 8.3). Potential users in contexts with similar national health services with a remit for providing adequate care for all citizens within a set pool of resources may have similar perspectives to those studied here; however, the findings cannot be directly applied to other countries without supplementary analysis of strategic support, piloting and existing uses of the technology. Data analysis conducted in this study gave attention to the strategic framework and health infrastructure into which PHM is being deployed, meaning that any attempt to transfer the results of the study to another context will require a similar analysis.

With that said, the conceptual analysis undertaken in the project may more readily transfer to contexts beyond England and the NHS. The framework is based on theories of virtue, surveillance and colonisation not bound to any particular context (see: Section 4.4.4). If similarities can be identified between contexts in terms of the colonisation of the patient's lifeworld by institutional medical concerns, the ends and virtues of medicine, the healing relationship, or implications of collecting and storing monitoring data such as social sorting of users, then the theories should apply equally well to other contexts. Additionally, the applicability of the conceptual framework across contexts is reliant upon the usage of similar technologies as defined through the categorisation of PHM developed above (see: Chapter 2). The fact that PHM is not developed for use in any particular country, and that the theories bound together in the conceptual framework are not dependent upon any particular location, gives reason to believe the conceptual contributions of the project are applicable beyond the context of study.

10.5.3 NRES

Finally, the NHS ethics approval process (NRES) proved a significant limitation to the research (see: Section 8.4.1). Taking more than 18 months from start to finish, the lengthy process curtailed the design of the study in terms of data collection and recruitment (see: Section

8.4.2). NHS telehealth and telecare pilot programmes providing alternative channels for recruitment, assuming a sample consisting of users of technologies related to PHM would be desired (see: Section 10.5.1), were eventually identified after speaking with local care commissioners in the final stages of the study (see: Section 5.3.1). Conversations with commissioners could only commence once NRES approval had been granted, so even if recruitment of samples from pilot programs would have been desirable, it could not have been carried out without submitting a revised NRES application. While this did not prove a significant limitation for the quality of the study considering the limitations of recruiting a sample of telehealth or telecare users (see: Section 10.5.1), it did limit the range of potential samples, and therefore must be mentioned as a limitation. Ideally NRES would be revised to significantly shorten the time between application and decision, allowing research to be carried out on current topics or technologies of interest prior to or soon after deployment.

10.6 Future Research

The limitations identified above suggest future avenues for research. Building on the results of this research, future qualitative hermeneutic studies of patient attitudes regarding ethical implications of PHM for personal and medical relationships can be conducted with current users of the technology. Opportunities for such research will continue to increase as PHM broadly moves from piloting to deployment. This type of research can reveal whether the attitudes encountered here are shared across different samples experienced with different PHM applications. Other cohorts of patients can also be researched, particularly those targeted by current piloting such as COPD. The importance of control and other themes seen in the fieldwork conducted here can be explored in such studies, providing a basis for expanding the conceptual framework to include autonomy or other concepts which help make sense of the desire for control (see: Section 9.4.3.1)

At a broader level, research should be conducted concerning patient attitudes towards the shift to self-care and self-responsibility enacted through technologies such as PHM, as it may conflict with the ideal model for medical relationships favoured by patients (see: Section 5.4). The existing assumption is that patients will welcome monitoring if it is presented as improving the quality of care they receive; whether patients will accept the underlying sense of self-responsibility to monitor their health is unclear.

Aspects of the research described here can also be expanded going forward. Research into the reasons for the superficiality of privacy discourses among PHM developers and security architects (see: Section 3.3.4.1) would be helpful in prescribing solutions to the problem; for example, ethics may be viewed as a 'checklist' in system development, whereby claiming that the system is privacy enhancing or secure is sufficient for the system to be considered 'ethical'. The existence of similar theoretical superficiality in discourses concerning related (emerging) technologies could also be investigated.

Finally, the main type of research which will be required in the future will concern the applicability of the conceptual framework to future discourses concerning the ethical implications of PHM in particular contexts. As recommended by the framing projects and the research reported here, future context-specific ethical assessment is necessary to respond to the ethical problems caused by future PHM applications, the details of which cannot be fully anticipated proactively. In other words, proactive ethical assessment is not enough—it provides a foundation for future ethical analysis. As suggested throughout, the conceptual framework provides a theoretical lens through which future context-specific research can occur, with the aim of helping stakeholders to understand one dimension of the moral potential of PHM: its implications for personal and medical relationships. In future research, the framework may help make sense of the ethical issues and normative claims encountered in relation to specific applications, both for researchers and stakeholders involved in ethical discourses.

10.7 Conclusion

The research described in this thesis contributes significant theoretical and empirical understanding to the moral potential of PHM in terms of implications for personal and medical relationships. Through a variety of research approaches the understanding developed is credible in both a theoretical and methodological sense, providing a new contribution to knowledge in several areas: (1) an ethical categorisation of PHM; (2) a conceptual framework for understanding one dimension of the moral potential of PHM which is amenable to future research; (3) an epistemological explanation of the difficulties and possibilities for ethically assessing the future through empirical research; (4) and a methodology for combining empirical and theoretical data in ethical analysis. The research leading to these contributions was methodologically rigorous and appropriately informed by existing research and background ethical, social and epistemological theories. An approach based on self-criticism

(see: Section 6.1.3.2) was taken to reflexively identify the prejudices implicitly in coming to understand the research topic, and to understand the importance of such prejudices in producing credible research.

As should be the case with self-aware research, the understanding developed here is not seen as an endpoint, representing instead a starting point for further research informed by a theoretical understanding of the moral potential of PHM. The research has gone some way in filling the 'conceptual vacuum' into which PHM continues to emerge; development must precede theoretical understanding of a technology (see: Section 7.3), but ideally the vacuum will be filled to a sufficient degree before widespread usage. In responding to the difficulties of uncertainty, such theoretical understanding goes some way to proactively identifying and responding to ethical implications in future contexts. The project therefore made contributions of practical utility to future research, development and governance by providing a novel theoretical lens through which the technology may be viewed. While the practical utility of the project's contribution to future research and discourses must remain to be seen, the outcomes of the project should be seen as highly credible, produced through a theoretically and methodologically rigorous approach to ethical analysis of PHM operating within the limitations posed by uncertainty. As has been said before, the position of uncertain proactivity is preferable to reacting to ethical problems as they occur (Stahl 2011a); the research conducted here gives a practical demonstration of how proactive assessment can advance ethical understanding of emerging medical technologies, employing a novel theoretical lens to do so.

11 References

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Appendix 1: Literature Review Tables

Table 1.1 - Sub-Categories of PHM⁹⁹

Category of PHM	Description	References
Mobile Monitors (n = 38)	Devices and sensors carried or worn by the user, ex vivo monitors.	Welsh et al. 2003; Brey 2005; Tentori et al. 2006; Bagüés et al. 2007a; Friedewald et al. 2007; Lauriks et al. 2007; Melander-Wikman et al. 2007; Monahan & Wall 2007; Rigby 2007; Robinson et al. 2007; Yuan et al. 2007; Casas et al. 2008; Fellbaum 2008; Jea et al. 2008; Demiris et al. 2009; Dorsten et al. 2009; Gammon et al. 2009; Gaul & Ziefle 2009; Pentland 2009; Fragopoulos et al. 2010; Giannotti & Saygin 2010; Kosta et al. 2010; Landau, Auslander, et al. 2010; Landau, Werner, et al. 2010; Lim et al. 2010; Wilkowska et al. 2010; Ziefle & Röcker 2010; Agraftioti et al. 2011; De Bleser et al. 2011; Boulos et al. 2011; Chakraborty et al. 2011; Garcia-Morchon et al. 2011; Giannetsos et al. 2011; Kovach et al. 2011; Mana et al. 2011; Mittelstadt et al. 2011; Rhode 2011; Nordgren 2012
Environmental Monitors (n = 82)	Devices and sensors embedded in an environment, such as a home, vehicle, or workplace, or a stationary medical appliance.	Lyon 2001; Welsh et al. 2003; Demiris et al. 2004; Hilty et al. 2004; Melenhorst et al. 2004; Neild et al. 2004; Agree et al. 2005; Brey 2005; Beaudin et al. 2006a; Caine et al. 2006; Tentori et al. 2006; Ahamed, Talukder & Haque 2007; Ahamed, Talukder & Kameas 2007; Coughlin et al. 2007; Courtney et al. 2007; Friedewald et al. 2007; Fugger et al. 2007; van Hoof et al. 2007; Lauriks et al. 2007; Mahoney et al. 2007; Martin et al. 2007; Rashid et al. 2007; Rigby 2007; Bagüés et al. 2007b; Casas et al. 2008; Chan et al. 2008; Courtney 2008; Courtney et al. 2008; Demiris et al. 2008; Essén 2008; Fellbaum 2008; Kenner 2008; Mitseva et al. 2008; Rialle et al. 2008; Srinivasan et al. 2008; Stuart et al. 2008; Vuokko 2008; Armac et al. 2009; Caine 2009; Chan et al. 2009; Coughlin et al. 2009; Demiris 2009; Demiris & Hensel 2009; Dorsten et al. 2009; Gentry 2009; Islam et al. 2009; Little & Briggs 2009; Massacci et al. 2009; Acharya 2010; Acharya & Kumar 2010; Bagüés et al. 2010; Busnel & Giroux 2010; Giannotti & Saygin 2010; McIlwraith et al. 2010; Nefti et al. 2010; Niemeijer et al. 2010; Ojasalo et al. 2010; Remmers 2010; Stowe & Harding 2010; Tiwari et al. 2010;

⁹⁹ These categories occasionally overlap, as some devices do not neatly fit in either such as assistive robots (Wu et al. 2012) or a smart pill box (Kosta et al. 2010). Furthermore, individual systems (e.g. smart homes) could incorporate features of both categories.

		Wilkowska et al. 2010; Ziefle & Röcker 2010; Bowes et al. 2011; Ding et al. 2011; Elkhodr et al. 2011; van Hoof et al. 2011; Leone et al. 2011; McLean 2011; Mittelstadt et al. 2011; Niemeijer et al. 2011; Palm 2011; Rhode 2011; Rigaud et al. 2011; Sadri 2011; Townsend et al. 2011; Ziefle et al. 2011; Zwijsen et al. 2011; Collste & Verweij 2012; Nordgren 2012; Sanders et al. 2012; Sorell & Draper 2012; Wu et al. 2012
Implantable Monitors (n = 4)	In vivo monitors.	Friedewald et al. 2007; Monahan & Wall 2007; Gaul & Ziefle 2009; Dhukaram et al. 2011
Other/Ambiguous (n = 9)	Generic PHM technologies or artefacts identified (e.g. telecare), but not specific applications. ¹⁰⁰	Hensel et al. 2006; Percival & Hanson 2006; Pallapa et al. 2007; Kaplan & Litewka 2008; Wang et al. 2008; Garcia-Morchon et al. 2009; Steele et al. 2009; Subramaniam et al. 2010; Salih et al. 2011

¹⁰⁰ The distinction between technology, artefact, and application describes a spectrum of developments from generic to specific. Ethical issues arising from specific contexts of use can only arise at the application level. For more, see: Brey 2011.

Table 1.2 - Demographics of Target Users¹⁰¹

Demographic	Description	References
Elderly (n = 74)	Target audience described as 'elderly' or 'older'.	Welsh et al. 2003; Demiris et al. 2004; Melenhorst et al. 2004; Neild et al. 2004; Agree et al. 2005; Caine et al. 2006; Hensel et al. 2006; Percival & Hanson 2006; Ahamed, Talukder & Kameas 2007; Coughlin et al. 2007; Courtney et al. 2007; Friedewald et al. 2007; Fugger et al. 2007; van Hoof et al. 2007; Lauriks et al. 2007; Mahoney et al. 2007; Martin et al. 2007; Melander-Wikman et al. 2007; Rashid et al. 2007; Robinson et al. 2007; Bagüés et al. 2007b; Casas et al. 2008; Chan et al. 2008; Courtney 2008; Courtney et al. 2008; Demiris et al. 2008; Essén 2008; Fellbaum 2008; Kenner 2008; Rialle et al. 2008; Stuart et al. 2008; Armac et al. 2009; Caine 2009; Chan et al. 2009; Coughlin et al. 2009; Demiris 2009; Demiris et al. 2009; Demiris & Hensel 2009; Dorsten et al. 2009; Gaul & Ziefle 2009; Gentry 2009; Islam et al. 2009; Little & Briggs 2009; Massacci et al. 2009; Steele et al. 2009; Busnel & Giroux 2010; Landau, Auslander, et al. 2010; Landau, Werner, et al. 2010; McIlwraith et al. 2010; Nefti et al. 2010; Niemeijer et al. 2010; Remmers 2010; Stowe & Harding 2010; Tiwari et al. 2010; Wilkowska et al. 2010; Ziefle & Röcker 2010; Bowes et al. 2011; Ding et al. 2011; van Hoof et al. 2011; Leone et al. 2011; McLean 2011; Mittelstadt et al. 2011; Niemeijer et al. 2011; Palm 2011; Rigaud et al. 2011; Sadri 2011; Townsend et al. 2011; Ziefle et al. 2011; Zwijsen et al. 2011; Collste & Verweij 2012; Nordgren 2012; Sanders et al. 2012; Sorell & Draper 2012; Wu et al. 2012
Non-Elderly/Ambiguous (n = 44)	Target audience age not described.	Berdichevsky & Neuenschwander 1999; Hilty et al. 2004; Beaudin et al. 2006a; van De Garde-Perik et al. 2006; Tentori et al. 2006; Ahamed, Talukder & Haque 2007; Bagüés et al. 2007a; Friedewald et al. 2007; Monahan & Wall 2007; Pallapa et al. 2007; Yuan et al. 2007; Fellbaum 2008; Jea et al. 2008; Kaplan & Litewka 2008; Mitseva et al. 2008; Srinivasan et al. 2008; Stuart et al. 2008; Wang et al. 2008; Caine 2009; Garcia-Morchon et al. 2009; Moncrieff et al. 2009; Pentland 2009; Acharya 2010; Acharya & Kumar 2010; Bagüés et al. 2010; Fragopoulos et al. 2010; Giannotti & Saygin 2010; Kosta et al. 2010; Lim et al. 2010;

¹⁰¹ Samples often fit into multiple demographic groups for a single study, which is reflected in Table 2. The difference between samples involving Chronic or Acute Patient and Healthy samples is important: it demonstrates that not all PHM is being designed to enhance or supplement medical care, but also to provide feedback loops of behavioural and lifestyle information. For such systems, users need not be thought of as 'patients'.

		Ojasalo et al. 2010; Subramaniam et al. 2010; Agrafioti et al. 2011; De Bleser et al. 2011; Boulos et al. 2011; Chakraborty et al. 2011; Dhukaram et al. 2011; Elkhodr et al. 2011; Garcia-Morchon et al. 2011; Giannetsos et al. 2011; Mana et al. 2011; Mittelstadt et al. 2011; Salih et al. 2011; Ziefle et al. 2011; Nordgren 2012
Chronic Patients (n = 41)	Target audience with a chronic illness such as dementia or diabetes requiring long-term care.	Welsh et al. 2003; Caine et al. 2006; van De Garde-Perik et al. 2006; Ahamed, Talukder & Kameas 2007; Friedewald et al. 2007; van Hoof et al. 2007; Lauriks et al. 2007; Mahoney et al. 2007; Martin et al. 2007; Rashid et al. 2007; Robinson et al. 2007; Bagüés et al. 2007b; Casas et al. 2008; Fellbaum 2008; Kenner 2008; Rialle et al. 2008; Stuart et al. 2008; Armac et al. 2009; Chan et al. 2009; Coughlin et al. 2009; Gentry 2009; Islam et al. 2009; Massacci et al. 2009; Busnel & Giroux 2010; Fragopoulos et al. 2010; Landau, Auslander, et al. 2010; Landau, Werner, et al. 2010; McIlwraith et al. 2010; Ojasalo et al. 2010; Wilkowska et al. 2010; Dhukaram et al. 2011; Leone et al. 2011; Mittelstadt et al. 2011; Niemeijer et al. 2011; Rhode 2011; Rigaud et al. 2011; Ziefle et al. 2011; Collste & Verweij 2012; Nordgren 2012; Sanders et al. 2012; Sorell & Draper 2012
Acute Patients (n = 15)	Target audience with an acute health condition.	van De Garde-Perik et al. 2006; Beaudin et al. 2006b; Friedewald et al. 2007; Monahan & Wall 2007; Rigby 2007; Fellbaum 2008; Pentland 2009; Kosta et al. 2010; Wilkowska et al. 2010; Agrafioti et al. 2011; De Bleser et al. 2011; Giannetsos et al. 2011; Kovach et al. 2011; Mittelstadt et al. 2011; Nordgren 2012
Healthy/Ambiguous (n = 9)	Target audience not described in terms of health status, such as in informational or preventative PHM applications (e.g. lifestyle monitors).	Berdichevsky & Neuenschwander 1999; Hilty et al. 2004; Beaudin et al. 2006b; Bagüés et al. 2007a; Monahan & Wall 2007; Jea et al. 2008; Pentland 2009; Agrafioti et al. 2011; Boulos et al. 2011

Table 1.3 - Ethical Themes

Theme	Issues/Concepts	References
Information Privacy (n = 57)	Data privacy, security as privacy enhancing, right to control information about oneself	Melenhorst et al. 2004; Neild et al. 2004; Beaudin et al. 2006a; van De Garde-Perik et al. 2006; Percival & Hanson 2006; Tentori et al. 2006; Ahamed, Talukder & Haque 2007; Ahamed, Talukder & Haque 2007; Coughlin et al. 2007; Friedewald et al. 2007; van Hoof et al. 2007; Pallapa et al. 2007; Rashid et al. 2007; Bagüés et al. 2007b; Chan et al. 2008; Courtney 2008; Essén 2008; Jea et al. 2008; Mitseva et al. 2008; Stuart et al. 2008; Wang et al. 2008; Armac et al. 2009; Caine 2009; Chan et al. 2009; Coughlin et al. 2009; Demiris & Hensel 2009; Dorsten et al. 2009; Garcia-Morchon et al. 2009; Little & Briggs 2009; Massacci et al. 2009; Moncrieff et al. 2009; Pentland 2009; Acharya 2010; Bagüés et al. 2010; Busnel & Giroux 2010; Fragopoulos et al. 2010; Giannotti & Saygin 2010; Kosta et al. 2010; Lim et al. 2010; Remmers 2010; Stowe & Harding 2010; Subramaniam et al. 2010; Wilkowska et al. 2010; Agrafioti et al. 2011; Chakraborty et al. 2011; Dhukaram et al. 2011; Elkhodr et al. 2011; Garcia-Morchon et al. 2011; Giannetsos et al. 2011; Mana et al. 2011; McLean 2011; Mittelstadt et al. 2011; Rhode 2011; Sadri 2011; Salih et al. 2011; Townsend et al. 2011; Ziefle et al. 2011; Zwijsen et al. 2011
Personal Privacy (n = 30)	Right to be left alone, free of unwanted attention, lack of surveillance, right to personal space	Welsh et al. 2003; Neild et al. 2004; Beaudin et al. 2006a; Percival & Hanson 2006; Bagüés et al. 2007a; Coughlin et al. 2007; Friedewald et al. 2007; Pallapa et al. 2007; Rigby 2007; Courtney 2008; Essén 2008; Demiris 2009; Demiris & Hensel 2009; Gaul & Ziefle 2009; Little & Briggs 2009; Giannotti & Saygin 2010; Kosta et al. 2010; Landau, Werner, et al. 2010; Ojasalo et al. 2010; Remmers 2010; Stowe & Harding 2010; Tiwari et al. 2010; Wilkowska et al. 2010; Bowes et al. 2011; Ding et al. 2011; Mittelstadt et al. 2011; Sadri 2011; Ziefle et al. 2011; Zwijsen et al. 2011; Sorell & Draper 2012
Autonomy (n = 35)	Rights to freedom, independence, personal decisions, technological dependence	Welsh et al. 2003; Brey 2005; Beaudin et al. 2006a; Percival & Hanson 2006; Friedewald et al. 2007; Fugger et al. 2007; van Hoof et al. 2007; Martin et al. 2007; Monahan & Wall 2007; Rigby 2007; Robinson et al. 2007; Essén 2008; Kenner 2008; Demiris 2009; Demiris & Hensel 2009; Dorsten et al. 2009; Gaul & Ziefle 2009; Gentry 2009; Islam et al. 2009; Steele et al. 2009; Busnel & Giroux 2010; Kosta et al. 2010; Landau, Auslander, et al. 2010; Landau, Werner, et al. 2010; Remmers 2010; Stowe & Harding 2010; Tiwari et al. 2010; Bowes et al. 2011; Mittelstadt et al. 2011;

		Niemeijer et al. 2011; Rhode 2011; Townsend et al. 2011; Zwijsen et al. 2011; Sanders et al. 2012; Sorell & Draper 2012
Obtrusiveness & Visibility (n = 23)	Physical/psychological prominence, subversion, public visibility, psychological disappearance, covert monitoring, inadvertent monitoring, context-specific	Demiris et al. 2004; Melenhorst et al. 2004; Neild et al. 2004; Brey 2005; Hensel et al. 2006; Courtney et al. 2007; Robinson et al. 2007; Courtney 2008; Demiris et al. 2008; Essén 2008; Fellbaum 2008; Kaplan & Litewka 2008; Kenner 2008; Demiris 2009; Demiris & Hensel 2009; Landau, Werner, et al. 2010; Tiwari et al. 2010; De Bleser et al. 2011; Bowes et al. 2011; van Hoof et al. 2011; Mittelstadt et al. 2011; Townsend et al. 2011; Zwijsen et al. 2011
Stigma & Identity (n = 18)	Public/private stigma, self-esteem, group identification, aesthetics, community implementation, risk-taking, behavioural expectations, passive control	Percival & Hanson 2006; Beaudin et al. 2006b; Coughlin et al. 2007; Courtney 2008; Essén 2008; Gaul & Ziefle 2009; Steele et al. 2009; Remmers 2010; Tiwari et al. 2010; Bowes et al. 2011; Ding et al. 2011; van Hoof et al. 2011; McLean 2011; Mittelstadt et al. 2011; Rhode 2011; Zwijsen et al. 2011; Sanders et al. 2012; Wu et al. 2012
Medicalisation (n = 9)	Altered perceptions of home, health obsession, over-diagnosis, doctor-patient relationship	Beaudin et al. 2006b; Chan et al. 2008; Courtney et al. 2008; Demiris & Hensel 2009; Gentry 2009; Bowes et al. 2011; Mittelstadt et al. 2011; Zwijsen et al. 2011; Sanders et al. 2012
Social Isolation (n = 22)	Replacement of human care, supplementary care, lack of social interaction, social networking, informal carer burdens	Demiris et al. 2004; Agree et al. 2005; Percival & Hanson 2006; Friedewald et al. 2007; Chan et al. 2008; Kaplan & Litewka 2008; Demiris 2009; Gentry 2009; Pentland 2009; Niemeijer et al. 2010; Stowe & Harding 2010; Tiwari et al. 2010; Bowes et al. 2011; van Hoof et al. 2011; McLean 2011; Mittelstadt et al. 2011; Palm 2011; Sadri 2011; Zwijsen et al. 2011; Collste & Verweij 2012; Nordgren 2012; Wu et al. 2012
Delivery of Care (n = 10)	Care community surveillance, carer-patient power relationships, behaviour monitoring,	Percival & Hanson 2006; Monahan & Wall 2007; Kaplan & Litewka 2008; Kenner 2008; Vuokko 2008; Niemeijer et al. 2010; Remmers 2010; Tiwari et al. 2010; Mittelstadt et al. 2011; Collste & Verweij 2012

	information overload, job security, workplace surveillance	
Safety & Technological Need (n = 14)	Misdiagnosis, priority of carer beliefs, internal vs. external perceptions of need, developer claims, PHM enhancing health and well-being,	Neild et al. 2004; Lauriks et al. 2007; Courtney 2008; Courtney et al. 2008; Kaplan & Litewka 2008; Dorsten et al. 2009; Gammon et al. 2009; Landau, Auslander, et al. 2010; Landau, Werner, et al. 2010; Tiwari et al. 2010; Ding et al. 2011; Niemeijer et al. 2011; Rhode 2011; Sorell & Draper 2012
Risk (n = 6)		Hilty et al. 2004; Little & Briggs 2009; Lim et al. 2010; Nefti et al. 2010; Dhukaram et al. 2011; Giannetsos et al. 2011
Other (n = 22)	Informed consent, data mining, equity of access, surveillance, behavioural monitoring, white lies	<p>Informed Consent: Neild et al. 2004; Bagüés et al. 2007a; Martin et al. 2007; Kaplan & Litewka 2008; Kenner 2008; Chan et al. 2009; Demiris et al. 2009; Demiris & Hensel 2009; Gammon et al. 2009; Remmers 2010; Stowe & Harding 2010; Bowes et al. 2011; Mittelstadt et al. 2011</p> <p>Data Mining: Fellbaum 2008; Pentland 2009; Remmers 2010; Bowes et al. 2011</p> <p>Equity of Access: Demiris 2009; Kosta et al. 2010</p> <p>Surveillance: Friedewald et al. 2007; Mahoney et al. 2007; Monahan & Wall 2007; Pentland 2009; Monahan & Fisher 2010; Remmers 2010</p> <p>Behavioural Monitoring: Berdichevsky & Neuenschwander 1999; Fellbaum 2008</p>

Appendix 2: Data Protection Regulations

A2.1 UK Data Protection Act of 1998

In the UK, it is unclear how the UK Data Protection Act of 1998 governing personal and medical data will apply to data collected by PHM. In particular, it is not clear if data collected by lifestyle monitoring systems which can record “every move, every action, many bodily functions, activities of daily living, whereabouts, [and] comings and goings from the house” (Bowes et al. 2011), will be classified as ‘personal data’ or ‘sensitive personal data’ as defined by the Act. This confusion is the result of the complex definitions of “personal data” and “sensitive personal data” found in the Act. Under the Act’s definition, PHM data will be “personal data” if it is accessible by parties other than the patient and contains identifying information such as name, contact information, patient number, etc. By this definition it is likely some PHM data will be classed as “personal data” and therefore afforded limited protection in comparison to “sensitive personal data,” which is restricted to a greater degree. In this context PHM data will become “sensitive personal data” if it relates to the health of an identifiable individual; what is not clear is whether information relating to the daily movements, actions and bodily functions of individuals will be included in the Act’s definition of “health.” As a result, the possibility of misuse or undesired access to personal data is raised. This could be a significant ethical issue following widespread implementation of PHM (Bowes et al. 2011).

A2.2 EU General Data Protection Regulation

The EU General Data Protection Regulation (henceforth referred to as the ‘EU Regulation’), set to come into full effect in 2016, is intended to simplify and unify data protection regulation across the EU. The EU Regulation, issued in draft form by the European Commission in 2012, is set to replace the EU Data Protection Directive of 1995 (European Commission 2012). The change from a directive to regulation is significant; the EU Regulation will be immediately applicable to member states as a piece of legislation, whereas the directive merely directed member states to enact specific data protection measures at the national level. As such, data protection expectations need to be unified at a European rather than national level to avoid conflicts between the EU Regulation and existing legislation at the national level, such as the UK Data Protection Act of 1998. Currently, conflicts between national data protection

measures may occur when personal health data crosses national borders. A unified European approach would, ideally, solve such issues through a single legislative approach.

The EU Regulation appears to resolve the ambiguity seen in the DPA in the definition of personal health data, which suggests that it affords greater protection to PHM data, although this conclusion is based on an interpretation of the language in the EU Regulation by which attributive and referential uses of (anonymised) data are restricted (cf. van den Hoven 2008, pp.309–10). ‘Attributive’ uses of personal data may go unprotected under the Regulation, which is problematic because attributive uses of anonymous data can lead to identification, as in homeland security investigations and marketing (van den Hoven 2008, p.310).

Under the provisions of the EU Regulation, any data related to health is considered a ‘special category of personal data’ (European Commission 2012, Article 9), which is restricted to a greater degree than other types of data.¹⁰² Assuming a link between behaviours and health can be established, it would appear that processing of pervasive behavioural data will be restricted to a greater degree at the EU level. However, even if PHM data falls under this more restrictive categorisation, possibilities remain for data misuse and processing which redefines the ‘legitimate interests’ of the user.¹⁰³ For instance, Article 81 specifies that personal data related to health may be processed as long as it meets the ‘legitimate interests’ of the user, and is necessary for “other reasons of public interest in areas such as social protection, especially in order to ensure the quality and cost-effectiveness of the procedures used for settling claims for benefits and services in the health insurance system” (European Commission 2012, Article 81). While the language used requires interpretation, the EU Regulation appears to allow the processing of PHM data for personalised health insurance claims and premiums. This provision creates potentially conflicts with the user’s right to freedom from profiling intended to predict health (European Commission 2012, Article 20), although the right only exists in the context of ‘automated processing’ and can be dismissed in cases in which a contract exists between user and data custodian which requires profiling. On this basis, it would appear that the forthcoming EU Regulation offers little protection against personalised

¹⁰² In the Data Protection Directive of 1995, personal data related to health is referred to as ‘sensitive personal data’ (Article 8).

¹⁰³ The term ‘legitimate interests’ is used throughout the General Data Protection Regulation, but is never defined. It appears to refer to the interests different parties have in the lawful processing of data. ‘Legitimacy’ would then be defined by the restrictions on data processing specified throughout the Regulation.

health insurance premiums and the pervasive profiling of PHM users into predictive health categories.

Another provision with potential implications for user expectations of privacy is the long-term storage of identifiable personal health data, which is allowed for research, statistical, or public health purposes (European Commission 2012, Articles 5, 83). As the research aims of the future cannot be known with certainty in the present, it is impossible for users to foresee the social and medical implications of research involving PHM data. Future research can impact on the medications and treatments available to patients in different healthcare systems, and contribute to new categories of disease or health profiles by which patients are diagnosed and treated.

The potential for violations of expectations of privacy may be mitigated through the rights attributed to users in the EU Regulation, including the aforementioned right to freedom from profiling, as well as the 'right to be forgotten'. The latter gives users the right to request deletion of their data at any time. It also specifies that personal data must be deleted when it no longer serves a legitimate purpose for the data custodian. While this right initially appears to grant users a powerful mechanism of data control, it relies both upon the user being aware of his rights granted under the EU Regulation, and understanding the content of the data stored about him, and by whom. In a future increasingly characterised by ambient and ubiquitous computing, in which the frequency of data collection and processing is predicted to greatly increase (cf. Brey 2005), it is unclear that users will know the identity of data custodians, and the extent of personal data held. While the 'automatic deletion' of data may protect the right to be forgotten in some instances, the opportunity exists for extensive, indefinite storage of personal health data on the basis that it may be useful for research or public health purposes in the future.

Given the possibility of user ignorance of the potential uses and value of PHM data, and the dubious protection afforded by the right to freedom from predictions of health against uses of personal health data beyond those found acceptable by users, it seems appropriate to advocate privacy protecting mechanisms beyond the provisions present in the EU Regulation. While the EU Regulation is built around 'fair information' principles which restrict the interaction between data custodians and creators (cf. The Caldicott Committee 1997), ensuring (for example) that appropriate consent procedures are followed and data collection has an

explicit purpose and endpoint, these principles do not appear to address the concerns identified above. Other protection mechanisms, including security measures such as encryption algorithms and system architectures which protect against data interception and manipulation (cf. Acharya 2010; Elkhodr et al. 2011), do little to assuage these concerns which are unrelated to the security (or quality) of data.

A2.2.1 Data Protection and Security

Security measures, such as encryption algorithms and system architectures which protect against data interception and manipulation, are insufficient by themselves to guarantee the privacy of data (Giannotti & Saygin 2010, p.77). The risks mentioned here in relation to data protection legislation present privacy risks unrelated to the security (or quality) of data. Principles of data processing and storage, such as those found in the EU Regulation, are needed to protect data privacy beyond the affordances offered by security measures. As seen in the reviewed literature, current discourse is overwhelmingly focused on ‘designing for security’; future system and security design needs to adapt to the ‘fair information’ principles and provisions adopted in the EU Regulation. The challenges presented by pervasive collection, processing and storage of personal health data necessitate a holistic approach in which systems incorporate features and security architecture designed to promote the privacy rights of users as outlined in relevant data protection legislation. DP mechanisms are lacking which empower the user to restrict predictions made about their health, and enforce temporal limitations on their data when lacking knowledge of where and how their data is being stored. User-end privacy policies may provide the type of user empowerment which appears necessary to overcome the ambiguities of the protection mechanisms, or ‘rights’, set to be enacted by the EU Regulation (see: Section 3.3.3.2), although the difficulties of informing users of the value and potential uses of their data remains ethically problematic (see: Section 3.3.3.1.1).

Appendix 3: Awareness and Expectations of Privacy

The problem of whether users must 'care about' privacy violations hints at the how violations of privacy can be understood (within the limits of PHM discourse) as a reflection of the individual's expectations. According to Nissenbaum (2004), to say privacy is violated is to say context-specific norms of privacy have been violated. Another way of expressing this idea is that the user's *expectations* of privacy are violated. Individuals define subjective limitations on acceptable modes of access and influence others can have over (information about) them — these are expectations of privacy. In this way Physical Privacy (see: Section 3.2.1.2) can be enforced by locked doors which the user expects others not to open without permission; Social Privacy (see: Section 3.2.1.2) can be enforced by turning off a mobile phone with the expectation that others will be unable to contact the user; Informational Privacy (see: Section 3.2.1.2) can be enforced by signing a user agreement which limits the ability of a data custodian to disseminate personal information to other parties beyond the expectations of the user outlined in the agreement. In each of these examples the user is taking actions which reflect expectations of privacy appropriate to his subjective, context-specific needs (cf. Nissenbaum 2004).

Conceiving of privacy as enshrined in user expectations helps clarify whether awareness of the privacy violating act is necessary to say a violation has occurred. The case of a peeping tom peering into a private space, such as a bedroom, is illustrative. If the peeping tom is caught in the act, the user becomes aware of violations of his expectations and a violation of privacy has occurred. If, on the other hand, the peeping tom is not caught in the act, it can still be said that a privacy violation has occurred because the user's expectation of the bedroom as a private space (e.g. Physical Privacy), free from outside view, has been violated.

But what if the user does not care about privacy? What if, for example, the user views the bedroom as a public space and is happy to have the peeping tom looking in? In this case it would appear that the same act violates expectations of privacy for one person, but not for the other. This is to be expected when individuals are free to define context-specific expectations of privacy (cf. Nissenbaum 2004), but there is a catch; for the second case to be justified, it must be assumed that the user is aware of the potentially privacy violating act, and has been able to define expectations of privacy with regards to it. It is necessary to draw a distinction between not being bothered by a particular act, and being unaware of the act, as in the case of

PHM which creates easily minable data. To 'not be bothered' a user must be aware of the potential for privacy violations stemming from an act, for example choosing to use PHM, and form expectations of privacy by which the problematic acts are not seen as such within the user's subjective conception of privacy. If the user has not had this opportunity, then they are unaware of the act which potentially violates their privacy; in the case of the peeping tom, someone is looking into their bedroom without first knocking on the window to ask for consent. The former act can be justified, but the latter cannot.

A right to privacy can then be conceived of as a right to specify informed expectations of privacy in the face of unfamiliar phenomena, such as emerging technologies. The 'existence' of a privacy right is separate from the 'experience' of privacy. The importance of the distinction between the 'existence' and 'experience' of privacy lies in the analysis of privacy implications of technologies. Technologies, situations, social interactions and actions can be analysed in terms of privacy to identify when a violation of privacy may occur. Whether or not the violations identified are actually 'experienced' is irrelevant—the purpose of identification is to expose the 'trade-off' that occurs to realise the benefits promised by the technology. The trade-off itself may be morally desirable—on balance, the violation of privacy may be insignificant compared to the benefits offered by the situation, as is typically the case when personally identifiable information is required in healthcare interactions. However, tipping the balance in favour of the benefits of the technology does not diminish or eliminate its privacy implications. The same can be said for the 'experience' of privacy—not caring about or not experiencing a loss of privacy does not diminish or eliminate the loss at a philosophical or theoretical level (excluding the exceptions of Social and Physical privacy mentioned above). It is therefore coherent to speak of privacy violations apart from the cognitive experiences of user.

This is not to say that PHM must be halted based on the herculean task of ensuring users have the necessary information to specify 'informed' expectations of privacy; pre-defined privacy rules, set out in user agreements or consent forms, may be an acceptable middle ground which ensures sufficient 'user awareness' of potential violations of privacy. Rather, it is to point out that a significant potential exists to violate the privacy of users 'behind closed doors', or on the basis of information collected about users which is analysed beyond their awareness. If users are to be given a chance to specify expectations of privacy for PHM, they must be made aware of the potential uses of their data as they become apparent to data custodians.

Appendix 4: Tension between Cost-Effectiveness and Clinical Efficacy

A clear tension exists in decisions to adopt, reject or limit the use of innovations between clinical efficacy and costs. Recent NHS strategy documents emphasise the need to meet increasing care demands without concomitant increases in healthcare resource expenditures, both in terms of money and manpower (Department of Health 2010a; Department of Health 2010b; Department of Health 2011, p.8; Department of Health 2012). However, the influence of financial constraints is not as clear as this position suggests, as practitioners are urged elsewhere to identify clinical best practice apart from financial concerns, while simultaneously providing 'financially responsible care' along 'pre-determined care paths' (Department of Health 2011). In practice, clinical and financial efficacy may be considered together at the level of care commissioning, but not during clinical practice. The choices available to practitioners would then be constrained by financially responsible commissioning, while actual treatments and care pathways within the range available to practitioners would not account for finances. A tension exists, then, between providing appropriate treatments and tools for clinically effective care while commissioning in a financially responsible manner, and in drawing an appropriate balance between the two. As emphasised throughout the strategy documents mentioned here, the importance of efficiency and cost-savings take centre stage in commissioning; what is unclear is how far this importance will constrain the choice of treatments available to practitioners at a local level.

The intention of the recent restructuring of the NHS is to "bring together responsibility for clinical decisions and for the financial consequences of these decisions" (Department of Health 2010a, p.27). Consortia and practitioners will be held financially accountable on the basis of the quality of care provided, guaranteed through inspections, adherence to 'best practice' guidelines and provisioning of budgets to meet local needs (Department of Health 2010a, p.27). GPs will be responsible for the financial implications, or efficiency, of their practice, which is intended to encourage innovation and improved management of chronic illnesses and costly conditions. Care and treatments which are not seen to 'add value', or have 'demonstrable' effects for patient health and healthcare, can be eliminated on a practice-to-practice basis (Department of Health 2010a, p.27).

The implication of this position is that separating the two allows for commissioning of treatments that are clinically ineffective but cheap or clinically effective but expensive, or out-of-sync with local care needs. Bringing practitioners into the 'commissioning fold' is seen as a way to solve these problems. However, there is a risk that practitioners may get stuck in commissioning only familiar treatments, or those with clear clinical and financial effects backed by empirical evidence. A sort of evidence-based 'treatment conservatism' is therefore a risk of the new commissioning structure, by which innovations fail to diffuse because of an initial lack of evidence demonstrating clinical and financial efficacy, or evidence which is applicable to local contexts.¹⁰⁴ On the other hand, focusing practitioners on the financial consequences of their actions risks infecting clinical decisions with financial motives; GPs are to be held accountable for their finances under the new commissioning structure, but simultaneously asked not to 'ration' care on a patient-by-patient basis, meaning more expensive diseases may become less treated. Furthermore, if the value provided by the GP comes to be understood purely from a clinical perspective, meaning value can be 'measured' in health parameters and outcomes, there is a risk that other beneficial aspects of medical care which cannot be demonstrated in clinical terms or RCTs will be eliminated from practice in the name of efficiency. As an example, telecare and telehealth may reduce face-to-face encounters with health professionals and family, replaced by machines capable of providing the same clinical measurements but lacking the ability to socially and physically engage the socially embodied patient.

Currently, resources are "directed towards priorities" to meet the "almost unlimited demand" on a nationalised health system with limited resources (Fitzgerald et al. 2002, p.1443). As a result, innovations in "non-priority areas," or ones which create additional demands on resources may fail to be adopted (Fitzgerald et al. 2002, p.1443), regardless of clinical effectiveness. However, financial incentives can greatly affect the likelihood of adoption (Salaman & Storey 2002), particularly "where the innovation requires the alteration of modes of service delivery and shifts work across professional or organisational boundaries" (Fitzgerald et al. 2002, p.1443). This aspect of diffusion is certainly relevant to PHM, which increasingly shifts care burdens to community and personal settings (such as the home) and away from clinical encounters with practitioners to remote monitoring, while being widely tested in the

¹⁰⁴ For example, RCTs are criticised for lacking generalizability to specific contexts of use. NICE guidelines are heavily reliant on RCTs, suggesting that consortia may be unable to find context-specific evidence to justify commissioning of innovations.

UK (see: Section 5.3.1) and financially supported throughout the EU (Empirica & WRC 2010) in the form of telecare and telehealth innovations.

Appendix 5: Problems with Shared Decision-Making under ‘No Decision about Me without Me’

An overly simplistic view of the patient-provider relationship is presented in the ‘Equity and Excellence’ White Paper (Department of Health 2010a, p.13); shared decision-making relies upon the patient’s ability to comprehend and compare evidence presented according to the provider’s values. In the NHS’ vision of this relationship, the appropriate balance between patient and provider values is unclear; the presentation of ‘evidence’ implicitly incorporates the values of the provider (cf. Molewijk et al. 2003), for example in the choice of evidence seen as relevant to the patient’s case. Furthermore, a patient incapable of rationally weighing evidence and coming to a care decision may make less clinically effective decisions—in such cases, should the provider ‘push’ the patient towards the ‘correct’ decision?

The principle emphasises transparent access and sharing of care records by patients. This structure is seen to guarantee a central role for the patient in the ‘shared decision-making’ model of care (cf. Emanuel & Emanuel 1992), while allowing the patient to ensure the accuracy of their care record. There are numerous problematic assumptions behind the assumed efficacy of the principle. First, it is unclear whether patients will possess the training or knowledge necessary to interpret and understand their care record. Furthermore, patients who fail to understand the implications of sharing their record, or are unable to determine between (in)appropriate recipients of their records, are placed at risk of having their data shared and used inappropriately. Second, even where records are understood and shared appropriately, the principle fails to provide real-time transparency in the decisions and judgments made by medical professionals on the basis of the care record. It is unclear whether, for example, a patient being placed into a risk category or disease group, perhaps on the basis of the novel health trends and patterns identified from newly linked and aggregated data, will always be notified of the categorisation. If, for example, the categorisation is made within an NHS practice or database, it is unclear whether the contents and categories of the database will be considered part of the patient’s care record to which they are guaranteed access. Even if categorisations are included in the care record, it would appear that patients require significant vigilance in monitoring their records to understand the decisions being made about them on the basis of their data, outside of face-to-face clinical encounters; guaranteed access cannot protect against such difficulties by itself.

Appendix 6: Truth as Moral Justification

To say something is true is to say that we, as interpreters, are confident that it is correct.

Truth is a positive claim to the correctness or a premise; claims can be the product of individual or communal agreement to some standard or criteria for truth. Truth claims in the natural sciences, however, are negative by nature under the critical rationalist paradigm of falsifiability. Inductive reasoning, core to the empiricist scientific method, is unable to prove the truth of any theory through testing; rather, the aim is to falsify or refute theories (Popper 1959; Popper 2002). Truth therefore consists only in theories which have not yet been refuted—no theory is ever proven conclusively true. Repeated testing, duplication of results, and refinement through empirical insights can strengthen the relative validity granted to a theory, but at best the theory will only ever achieve the status of a well-tested, but not yet refuted, ‘truth’ (Bauman 1978, p.238).¹⁰⁵ To understand the importance of truth in science, it is better to conceive of truth not as absolute, positively proved theories, but as an unreachable ideal which guides scientific inquiry. Truth is a goal for science to strive towards—whether or not it is ever reached in practice is inconsequential to the value of the endeavour (Popper 1959). Truth must therefore be viewed within the natural sciences as “an objective and not mistaken for a description of a specific state of things reached here and now” (Bauman 1978, p.238). Within hermeneutics and its search for ‘true understanding’, truth plays the same role. In both cases, truth acts as “the guiding principle of the on-going rational discussion, resulting every once in a while in rationally substantiated agreements” (Bauman 1978, p.239). Truth is a ‘standard of belief,’ providing grounds for agreeing upon correct ‘interpretations of meaning’ between parties in a discourse. Although the interpretations cannot fully meet the standards of truth, rational discourse can ‘prove’ that alternative interpretations adhere closer to the shared standards of truth or validity criteria, providing reasons for acting as if the interpretations are true.

For truth to justify actions, cultural consistency or intersubjectivity between participants in discourse must be assumed at some level: as Habermas notes, hermeneutic statements “grasp interpretations of reality with regard to possible intersubjectivity of action-orienting mutual understanding specific to a given hermeneutic starting point” (Habermas 1972, p.195).

Dialogue therefore assists in the pursuit of agreement on correct interpretations by facilitating

¹⁰⁵ In this scientific paradigm, scientific laws are theories shown to be overwhelmingly valid through the accumulation of empirical observations. They are, however, still falsifiable.

communication between humans. Although, as with the natural sciences, hermeneutics cannot prove “the truth of intersubjective agreement,” it can play a critical role by identifying “conditions of communication which lead to an invalid, untrue consensus” (Bauman 1978, p.241). Hermeneutics moves humans closer to truth in intersubjective agreements by identifying instances and conditions of invalid consensus.

As the ideals of rational discourse cannot be fulfilled in practice, given the impossibility of transcending one’s unique perspective or ignoring one’s forestructure of understanding, universal (generalisable) truths remain forever out of the grasp of social research.¹⁰⁶ However, in treating rational discourse as an ideal, participants in dialogue can arrive at provisional truths and theoretical claims which can be transferred across contexts and phenomena with appropriate supporting rational argumentation or discourse. It is in this sense that the outcomes of rational discourse are ‘generalisable’. All hermeneutic understanding is provisional, as required by the continuous expansion of the hermeneutic circle (Bauman 1978, p.235). This, however, does not need to pose an epistemic problem for hermeneutics and rational discourse; recall that, as with scientific knowledge developed through falsification, absolute truths are not required for cooperative life (Gadamer 2004). Rather, all that is needed is acceptance of consensus upon which human action can be justified. The circle thus never needs close for hermeneutics research to provide justified norms of conduct attained from the pursuit of rational discourse.

This account of truth is not meant to disparage rational discourse as a method to attain moral truth; rather, it shows that according to the ontological and epistemological commitments of hermeneutics, acontextual, universal truth is a fundamentally flawed concept. Truth therefore needs to be redefined to recognise the inherent limitations of historically and contextually-bound human understanding. The pursuit of truth can be understood as the pursuit of ‘true meaning’ or ‘true understanding’, yet these are incoherent concepts because meaning and understanding can only be shown to be incorrect (through dialogue) within specific contexts. Context-free meaning is impossible: “the fullest understanding one can think of is still context-dependent and context-confined” (Bauman 1978, p.230). This does not doom humans to moral relativism—generalisations and theories can be comprehended in contexts, while still being transferrable or applicable to multiple contexts. The view that “hermeneutics implies

¹⁰⁶ The same could be said for all social and natural sciences, and human knowledge in general, with the exception of pure deductive reasoning as seen in theoretical mathematics (Popper 1959; Hume 1978)

that in practical situations one *can* distinguish between right and wrong, not on the basis of objective criteria but through *practical experience* and on the basis of *communication and deliberation*” has been defended by Gadamer (1960), Ricoeur (1983) and Habermas (1991) as a way to move beyond the objectivist-relativist dichotomy (Widdershoven 2005, p.58) through pursuit of the ideal of truth in rational discourse.

Appendix 7: A Rejection of Rigour

Attempts have been made to adapt positivist validity criteria to interpretive research in the form of 'rigour'. The turn is meant to move interpretive research away from positivism, focusing instead on the uniqueness of the methods and goals of social research. Rigour is a judgment of the honesty, transparency and reflexivity demonstrated in the research process and outcomes; it is often described in terms of 'trustworthiness' or integrity (Finlay 2006, p.7). Different accounts of rigour reveal the extent to which criteria are still based on positivistic validity rather than reflecting an interpretivist or hermeneutic epistemology.

Lincoln and Guba (2000) describe *credibility*, *transferability*, *dependability* and *confirmability* as criteria of validity in (interpretive) qualitative research. The latter is the adaptation of objectivity to qualitative research, achieved through reproducibility, which refers to the reproduction of results with similar participants in a similar context to establish the validity or "truth value" of the study. However, the expectation of reproducibility is inappropriate because "qualitative studies by their nature cannot be replicated because the real world changes" (Marshall & Rossman 1999, p.195). They also suggest that the findings should represent the views and beliefs of the participants, yet there is an aura of objectivity about this criterion in the assumption that the researcher could *merely reproduce* the beliefs of participants without re-interpreting them, as is claimed by hermeneutics.

Mays and Pope (1995) suggest minimising researcher bias in the presentation of results by clearly distinguishing between the data, analytic framework and interpretation. This approach is incoherent in the hermeneutic tradition, as data does not exist independently of the interpretation of the researcher. Transcribed utterances must be interpreted before they have meaning, so the data and the interpretation are one in the same. With this said it is important to be as clear as possible about the influences and reasoning behind the interpretation.

Sources of researcher influence on the outcomes of qualitative research have been recognised as problematic, including the Hawthorne effect and the double hermeneutic (Finlay 2006, p.9; Kuper et al. 2008, p.687). According to this criterion, researchers should be forthcoming about their possible influence on the participants in an empirical study (Kuper et al. 2008, p.687) to highlight potential sources of bias. In positivistic studies it is typically desirable to avoid such influence, but paradigms which do not view researcher influence as problematic, such as hermeneutics, need only be concerned with reflexivity.

Triangulation, peer and respondent auditing have been proposed as ways of “validating” researcher interpretations (Mays & Pope 1995; Finlay 2006). The analysis of different sources of data which provide different perspectives on the phenomenon under study is said to increase validity in qualitative research (Mays & Pope 1995; Marshall & Rossman 1999, p.194; Kuper et al. 2008, p.688) by “reducing the risk of chance associations...and allowing a better assessment of the generality of the explanations” developed (Maxwell 1998, p.245). There is, however, no reason to expect similar interpretations from different people and methods because understanding is unique to the interpreter, reliant as it is on the forestructure of understanding and dialogue between texts and persons (Patterson & Williams 2002, pp.32–3). Therefore, whether or not similar interpretations emerge in attempts at validation is irrelevant to establishing the credibility of hermeneutic research. Despite the rejection of triangulation, multiple sources of information were considered throughout the research project: prior research projects (see: Chapter 1) and academic discourse (see: Chapters 2 and 3), DH and NHS strategy and pilot studies (see: Chapter 4) as well as the perspectives of potential users (see: Chapter 9).

The crucial difference to recognise between credibility and rigour is that while both are evaluations of the quality of research on the basis of its outcomes, rigour also claims that the integrity of the methodology contributes to the quality of the research in itself. Rigour can therefore be viewed as an attempt to introduce objectivity into qualitative research by deriving truth from methodological purity. Hermeneutics rejects this view, acknowledging that identical methods should not be expected to produce identical results in social scientific research due to the interpretive nature of all human experience. Credibility therefore derives truth entirely from evaluation of the research outcomes, as opposed to its method. With this said, methodological considerations can still factor into credibility, as a clear, reflexive description of the methodology assists in establishing the persuasiveness and practical utility of hermeneutics research. Rigour criteria can therefore play a secondary role in hermeneutics research—they do not contribute to the ‘truth’ of empirical research, but instead provide guidance for sufficient explanation of the research which improves the dialogue between reader and research text.

Appendix 8: Approaches to Integrating Empirical Data with Ethical Theory

This description of the empirical ethics mind-set breaks with previous work in the field by narrowing the scope of studies that can be labelled as empirical ethics. The refinement in scope is the result of a critical analysis of the treatment of empirical data and ethical theory in ethical analysis, according to which an iterative relationship between the two is necessary to label a study as empirical ethics. To see how the refinement of the empirical ethics label fits into the current field, it is worth outlining existing approaches to the integration of empirical data and ethical theory in ethical analysis. Molewijk et al. (2004) have outlined five such approaches, which have been assessed by Leget et al. (2009). The approaches “differ with respect to the way in which empirical data and ethical theory interact and the answer they provide to the question of whether moral theory, social practice or both possess the final moral authority” (Molewijk et al. 2004, p.55):

1. **Prescriptive Applied Ethics** – Moral theory is given foundational importance in examining social practices. Empirical data is not used to refine moral theory, but rather to determine if practitioners are behaving in a way which upholds or respects the theory. This is an example of a top-down approach.
2. **Ethicists as Theorists** – Moral theory has foundational importance, but can be refined or improved in light of normative empirical research. The relationship between theory and empirical data is “one-way,” in the sense that data is used instrumentally to refine theory. The emphasis is placed on theory building, rather than solutions for or insight into moral practices.
3. **Particularistic Ethics** – A bottom-up approach, in which social context is given foundational importance, which contrasts with prescriptive applied ethics. The “general acceptance of a practice by a community suffices as ethical justification of that practice” (Leget et al. 2009, p.231). Ethical theory does not play a role in considering social practices. The conclusions reached in this approach are valid only within a specific context, and cannot be applied to other practices. Casuistry is the best known approach to applied ethics that meets this description.
4. **Critical Applied Ethics** – A two-way relationship between empirical data and ethical theory, in which empirical insight into a practice and ethical theory are given equal consideration. The relationship is iterative in the sense that theory can be used to refine practice, and vice versa. Normative concepts such as ‘dignity’ can be used to analyse a practice, which may reveal that the concept requires refinement in light of its specification within the practice. In this sense the concept is given meaning through social practices, while a theoretical framework provides the initial content which is then refined. Once refined, the concept can then be related back to existing ethical theories to provide further theoretical support. Normative justification

ultimately relies on empirically informed ethical theory determining moral judgments (Leget et al. 2009, p.234).

5. **Integrated Empirical Ethics** – An intensified version of critical applied ethics in which the two-way relationship is dependent upon an “ongoing dialogue between descriptive social scientists and ethicists in which the distinction between fact and value eventually disappears” (Leget et al. 2009, p.231).

It is worth mentioning problems with a few of these conceptions of empirical ethics.

Particularistic Ethics amounts to little more than moral relativism if it is truly as insular as suggested by Leget et al. (2009), meaning appeals are not made to moral principles or ethical theories to justify decision-making. The distinction drawn between Critical Applied Ethics and Integrated Empirical Ethics is equally problematic—the latter is described merely as an ‘intensified version’ of the former, with little description in what this actually means. A better distinction may be possible on the basis of an emancipatory mind-set (cf. Stahl 2008; Stahl 2011). The two-way relationship between practice and theory suggests that both are amenable to revision on the basis of the other, which indicates an opportunity for emancipation from accepted practice-internal norms or specification of norms within a specific theoretical perspective. How this emancipation would occur in practice is unfortunately vague, as is the change in ‘intensity’ seen in integrated empirical ethics, although the collapse of the fact-value distinction suggests practice-internal norms and ‘virtues’ may play a greater role in the revision of theory.

To these approaches I would add a sixth approach, which I will call ‘holistic empirical ethics’. This category includes approaches to empirical ethics which adapt reflective equilibrium as a method for ethical analysis (cf. van Thiel & van Delden 2010; De Vries & van Leeuwen 2010), and which view the five models above not as distinct approaches to integration but rather different aspects of a holistic approach (Hurst 2010). Holistic empirical ethics expands upon the two-way relationship between empirical data and ethical theory in Critical Applied Ethics by requiring consideration of social and historical contextual information and the researcher’s perceptions, which are refined through dialogue with moral practitioners. The researcher exists as a third partner in the relationship between empirical data and ethical theory, emphasising the influence of the researcher’s frame of reference and interpretation of the data on the outcomes of the research. In holistic empirical ethics the three sources of information (empirical data, ethical theory and the researcher’s perceptions) must be refined and brought into coherence in reaching normative conclusions. Each source is given initial *a*

priori legitimacy which can only be confirmed through reflective equilibrium (Rawls 2001, pp.29–32), or a similar decision process.

Of the six general approaches, only the latter three should be given refined label of empirical ethics. The approach taken in this study is most closely aligned to the latter, holistic empirical ethics, albeit without a reflective equilibrium component. In adapting this label, which is meant to identify empirical ethics research in which empirical data, contextual information and ethical theory are given equal *a priori* legitimacy.

Appendix 9: Initial Credibility of the Normative Claims of Moral Practitioners

Moral wisdom is expressed to others in the form of normative claims. In other words, moral wisdom leads individuals to claim that a certain course of action or norm is the correct one when multiple actions or norms are available. Practice internal norms of good or justified actions are seen in 'moral intuitions', defined as "pre-reflective judgements about particular cases or situations" (van Willigenburg & Heeger 1989), which provide an initial indication of the correct 'direction' of a moral judgment (van Thiel 2009, p.68). Moral intuitions can be seen as the basis of some normative claims made by moral practitioners, and are an expression of prejudices based to some degree on moral experiences with a practice. Intuitions are initial reactions to morally challenging situations, coloured by the moral experiences encountered in a particular practice or case. Intuitions are not merely 'gut reactions' or immediate responses to a moral experience; they can be the product of a period of reflection, in which the morally relevant facts of the situation are considered alongside the "possible effects of different decisions." At this 'pre-reflective' level, intuitions are not influenced by dominant theories or principles, such as respect for autonomy (Rawls 1951, p.183; van Delden & van Thiel 1998, p.253); intuitions are non-inferential, in the sense that reflection occurs only at the general level of a case, prior to detailed reflection on individual morally relevant aspects and consideration of relevant moral principles or theories (Audi 1996, pp.112–3). Intuitions thus exist in the 'pre-reflective' space between immediate 'gut-reactions' to a case and detailed analysis of its individual components, which allows for a limited degree of reflection and rationality. The movement from intuition to moral belief through reflection can be seen in the movement from 'present-at-hand' to 'ready-to-hand' phenomena (Heidegger 1967), seen in hermeneutic understanding (see: Section 6.1.3.2).

It may be inappropriate to judge the reliability of initial judgments before the practitioner enters a process of reflection (van Delden & van Thiel 1998; van Thiel & van Delden 2010). This proposal is a result of the recognition that beliefs are often created by intuitions rather than an ideal process of deliberation and reflection, such as that described by Rawls in naming conditions conducive to reflection (1951; 1999). These beliefs, formed intuitively through automatic responses to challenges (Musschenga 2008, 132), are the basis of the prejudices by which moral situations are judged and interpreted. As a result, it is likely the moral wisdom of

practitioners in a morally challenging practice is formed on the basis of intuitions to some degree. It is these intuitive beliefs that provide insight into the moral experiences of practitioners and morally relevant aspects of a process (G. J. M. W. van Thiel and van Delden 2010, 189). Intuitive beliefs are therefore claimed to have a legitimate role in moral justification and theory building, such as is undertaken in refining the conceptual framework.

A9.1 Criticisms of Intuitions as a Source of Morality

Abstract ethical theories founded upon self-evident first principles often conflict with moral intuitions. The clash can be used as a reason to either ignore intuitions, or to argue against the acceptability of a theory. Criticism of intuitions as a source of morality tend to emphasise their weak normative foundation, seeing them as products of “superstition, bias, and mere historical accident...[which] should play no role in moral theory construction or justification” (Daniels 2011). Similar lines of criticism have been undertaken by philosophers, particularly utilitarians, for many years (Hare 1973; Singer 1974; Brandt 1998).

Advances in scientific understanding of brain imaging techniques and the evolutionary importance of ‘morality’ have provided further fuel to the critical fire. Studies into the structure of moral decision-making suggest that moral judgements begin with intuitive or automatic responses, occurring at a subconscious level of thought (Musschenga 2008), which is sometimes followed by a longer conscious reasoning process in which the initial judgement is rationalised (Haidt et al. 2000; Haidt 2001) or overturned (Greene et al. 2001), perhaps by appeal to ethical norms or principles.¹⁰⁷ If this structure of moral judgement is accurate, it provides an empirical basis for the distinction between moral intuitions and credible normative claims, with the latter defined by the process of reflection and appeal to abstract norms and principles. Crucially, this structure shows only that the process of moral deliberation is often

¹⁰⁷ It is worth saying more about the outcomes of these experimental explorations of moral reasoning, so as to not overstate the reach of their conclusions. Greene et al. (2001) showed that, in considering the classic “trolley problem,” people defending their intuitive reaction (the majority) showed increased activity in the area of the brain associated with emotions, whereas those which overturned their intuitive reaction (the minority) took longer to decide, and showed increased activity in the ‘cognitive’ area of the brain. Haidt (2000; 2001) showed that, in a variety of areas of moral reasoning, people tend to make judgements quickly through intuitive responses. When slower, cognitive reasoning is undertaken, it typically serves to rationalise the initial response, rather than overturn it by providing a new foundation for the moral judgement. While these studies are relatively limited, their findings are still important because they can be interpreted to undermine the ability of humans to engage in critical moral reasoning. However, the results of these studies are preliminary and represent a relatively small data set, so taking their conclusions as reliable descriptions of the role of moral intuitions in moral reasoning would be irresponsible. Still, if their conclusions prove justified, it is worth considering their impact on the normative weight we give to moral intuitions.

quick and intuitive; it does not undermine the existence or practical importance of practice internal norms and moral wisdom. Despite this, it has been used to criticise intuitions as a source of morality from an evolutionary perspective.

Updating criticisms of intuitionism with insights from evolutionary theory and neuroscience, Peter Singer argues that moral intuitions are mere cultural, religious and biological remnants of human development which express pre-reflective biases lacking normative force (Singer 2005). Under this conception, intuitions are not amenable to revision or argumentative force, meaning objective criteria for judging more or less morally acceptable intuitions do not exist. Singer seems to assume that humans are incapable of altering their moral judgements beyond their initial reactions to moral situations. This perceived weakness, combined with the evolutionary origin of norms of common morality, is taken as sufficient reason to strip moral intuitions of normative weight because intuitions lack the sort of 'reason-giving' or argumentative justification of a well-developed normative theory. Singer denies moral intuitions any role in moral deliberation, and condemns reflective equilibrium as a method for treating intuitions as "some kind of data from which we can learn what we ought to do" (Singer 2005, p.346). Instead, ethical deliberation should "ignore all our ordinary moral judgments," and deduce practical interventions from an abstract theoretical position. How such a method could be used to construct context-specific interventions acceptable to specific practitioners is unclear, but given that moral intuitions would lead to 'culturally relative' ethics (Singer 2005, p.346), it would appear specific interventions are in principle discoverable through the application of a single, abstract theory to real-world moral problems.

A9.2 Justificatory Power of Intuitions and Credible Normative Claims

Singer fails to recognise the utility of moral intuitions as initial guides to action, and the ability to improve or abandon (e.g. to justify) intuitions through critical revision. If humans are able to refine and justify their intuitions through appeal to abstract principles, theories and evidence, then relying upon intuitions for initial guidance in moral situations becomes less problematic, especially when intuitions are seen as more than by-products of evolution. This latter statement refers to hermeneutic understanding and prejudices which develop throughout life. If prejudices are built through past instances of moral decision-making, meaning they consist of a body of beliefs and evidence which have proven sufficient or justified in prior moral deliberation, then intuitions can be granted *initial* normative credibility

in future instances of deliberation through which the interpreter attempts to understand and make moral decisions about an unfamiliar phenomenon. The initial credibility of moral intuitions then is simultaneously undermined by its evolutionary origin, and supported by the ability of humans to engage in moral deliberation and critical revision of norms.¹⁰⁸ Singer seems to implicitly deny the possibility of the latter, which explains his call to strip intuitions of normative force. He describes moral intuitions as if they are the mere by-product of evolution, denying the possibility of a morality which develops throughout life. In a sense, he denies the possibility of 'learning' morality, expressed through intuitive responses.

The existence of practical-internal norms and practice-specific moral wisdom is not undermined by the realisation that moral judgements appear to consist of an intuitive reaction followed by cognitive rationalisation of that reaction. As long as evidence can be found of humans overturning their initial judgements through inner and interpersonal moral deliberation (Greene et al. 2001), we have reason to believe that moral practitioners can both engage in critical reflection and provide unique insight within moral deliberation. It would be odd to think that a person's experiences throughout life, especially within morally charged practices, do not change their norms of morally acceptable behaviour in any way. If the opposite were true, it would seem humans are born with a set of unchanging moral intuitions or norms derived from evolution which, although occasionally abandoned within specific instances of moral deliberation (Greene et al. 2001), nevertheless provide a fixed set of moral norms. In a sense, humans would be mere slaves to their genetic desires, rather than hermeneutic interpreters capable of developing knowledge, for example through dialogue.

What Singer's position makes clear is that the foundation of moral intuitions may be contentious when ethics is viewed as a means of moving beyond the limitations of nature—if we aim to lead better lives, defined by the ability to provide justified reasons for the actions we undertake, then it is helpful to know when our intuitions may merely reflect an evolutionary bias, of which we may wish to rid ourselves. Identified as such, appeals to

¹⁰⁸ A source of morality needs to be identified which provides humans with the capacity to engage in moral deliberation. Without this, the outcomes of these deliberations lack normative force. 'Moral wisdom' fulfils this role here; for Rawls, it was "moral capacity" (1999, p.46). Moral intuitions are therefore *initially* credible because they are created by humans with a capacity for moral understanding, developed through moral experiences. The latter is an assumption about human nature fundamental to social, cooperative living; morality loses its purpose unless we assume others have experiences and capacities similar to our own, which allow for cooperative moral deliberation.

‘evolutionary intuitions’ can be seen as the naturalistic fallacy in practice (cf. Hume 1978; De Vries & Gordijn 2009).

Appendix 10: Collapsing the Fact-Value Gap in Practice

Several research goals have been proposed as proof of the need to combine the descriptive and normative within empirical ethics, and to demonstrate the value empirical data can have in contextualising and developing ethical theory: (1) to assess implicit normativity in technologies or practices (cf. MacIntyre 2007, p.187), referring to their inherent normative content, such as the presentation of data to a patient considering a medical intervention¹⁰⁹ (Molewijk et al. 2003; Goldenberg 2005; De Vries & Gordijn 2009, p.196); (2) to improve the context-sensitivity and practical feasibility of ethical norms and principles through examination of empirical data, for example on the presentation of information to patients as a prerequisite of informed consent (De Vries & Gordijn 2009, p.195); (3) to identify important empirical questions through ethical analysis, which can be studied and iteratively fed back into ethical analysis (Musschenga 2005, p.469; McMillan 2008, p.17; Leget et al. 2009; De Vries & Gordijn 2009, p.194); (4) to ethically assess and develop morally acceptable interventions within the field of medicine, such as quality adjusted life years¹¹⁰, advanced directives, informed consent and ethics committee reviews (McMillan 2008, pp.17–18; De Vries & Gordijn 2009, p.194); (5) to critically assess how ethical norms are embedded in social structures and culture, thereby revealing morally questionable practices and their methods of concealment (Leget et al. 2009); and (6) to assess the moral beliefs of moral practitioners, during which researchers gather and analyse normative content and specify ethical concepts and principles through dialogue (Musschenga 2005, p.469; McMillan 2008, p.18; De Vries & Gordijn 2009, p.195; Widdershoven et al. 2009). In each of these types of research the data collected has normative content, whether resulting from implicit normativity or the moral experiences of moral practitioners involved in the research, and cannot be reasonably separated into normative and descriptive parts (McMillan 2008, p.17; De Vries & Gordijn 2009, p.194). When this epistemological realisation is considered with the contribution of empirical data to

¹⁰⁹ An in-depth discussion of implicit normativity in medicine is available in (Molewijk et al. 2003; Goldenberg 2005). According to Goldenberg (2005), “medical decision-making...draws upon a broad spectrum of knowledge, including scientific evidence, personal experience, personal values, economic and political considerations, and philosophical principles. It is not always clear how practitioners integrate these factors into a final decision, but what is clear is that medicine can never be entirely free of value judgments.” The concept of ‘health’ is also implicitly normative.

¹¹⁰ Empirical evidence may reveal deeper understanding of attitudes towards ethical interventions, such as the superficial measurement of respondent opinions towards QALY’s via survey techniques (Edgar 1995), or the cultural values by which health (and thus QALYs) are measured in specific cultures (Edgar 1997; Edgar 1998).

improving ethical analysis at all stages of research, the need for empirical ethics becomes clear.

The purpose of mentioning these goals is not to set criteria for labelling studies as “empirical ethics,” but rather to hint at the breadth of research in which normative content is present. In practice this means the six research goals mentioned above do not necessarily make a study an empirical ethics study; rather, studies must be judged on the basis of the researcher’s awareness and explication of the relationship between (and convergence of) the descriptive and normative within data gathering and subsequent analysis, as evidenced in the iterative relationship between empirical data and normative theory in ethical analysis.

Appendix 11: Validity, Certainty and Credibility

Validity, certainty and credibility have a potentially confusing relationship which requires further attention. Certainty should be understood along critical rationalist lines in terms of the standards by which the *validity* of normative claims is judged (cf. Popper 1959). Certainty is a summary of the validity of a statement, or the provisional truth of a statement established through falsification.

By the definition of certainty offered above (see: Section 7.3.1.1), uncertain claims are defined by a lack of falsifiability, meaning they lack validity. Recall that despite the name, Habermas' validity claims are better understood as evaluations of credibility because discourse seeks moral truth (see: Chapter 6.3.1). As the term is used here, uncertain claims refer to claims about the future. In this context, uncertainty is linked to phenomena beyond human understanding, due to the logical impossibility of knowing the future until it happens. Uncertainty can therefore be understood in terms of the failure of the claim to demonstrate its "rightness," or the validity of the future context it describes (Habermas 1984, pp.99–100). As the future is inherently unknowable, the validity of the statement in the context of the future cannot be judged. This lack of validity results from being unable to falsify the statement: (empirical) evidence cannot be produced about future phenomena, which are not directly observable. Uncertain claims thus refer to a future context beyond the logical limits of human understanding, for which direct observational evidence is unavailable. Despite this, uncertain claims must be taken seriously in discourse due to their influence on human action.

Certainty need only be seen as an ideal, defined by the distinction between validity and credibility (see: Section 6.3.1), or descriptive and prescriptive truth, to operate as an epistemic distinction separating claims about the future from claims about the present. The future eludes empirical observation. Statements about the future can therefore never be certain, or valid. While statements about the future can be based upon observations of the present (e.g. foresight), their accuracy in describing the future logically cannot be known. Despite a lack of validity, claims about the future can be judged credible when adhering to accepted standards of moral truth, understood along hermeneutic lines. For example, a claim could be derived from a specific possible future phenomenon. The claim need not be empirically valid for it to reach justified conclusions about a future that may occur—in other words, the claim would be credible in the future if the phenomenon eventually occurs as described.

Appendix 12: Proportionate Review

Two types of reviews are available from RECs based on the complexity of the ethical issues arising in the study. 'Proportionate review' is an expedited service undertaken by an REC sub-committee, as opposed to a full committee for 'full review'. Proportionate review studies aim to provide a decision on NRES applications within 14 days of receipt, as opposed to 60 days for full review. Proportionate review is available for studies with few ethical difficulties, including those which do not involve vulnerable adults, children or individuals potentially lacking the capacity to consent. As the original sample included dementia patients, the study had to undergo 'full review'. Following rejection of the first application, dementia patients were dropped from the study, and replaced by dementia carers. Importantly, the NHS was not asked to assist in recruiting dementia carers; for all purposes, dementia was eliminated entirely from the two subsequent applications (12/EM/0064 and 12/EM/0160) which was believed to improve the chances of the application being approved because the study would no longer contain individuals potentially lacking the capacity to consent (e.g. dementia patients). Once dementia patients were eliminated from the application, it was confirmed by the Leicester REC that the application would, in theory, be eligible for proportionate review. However, because the new applications were connected to the original application which involved dementia patients, proportionate review was not an option. This technicality proved serious for the timeline of the study; proportionate review undertaken in January 2012 when application 12/EM/0064 was submitted would have potentially reduced the NRES approval process by five months, as approval was only granted from full review at the end of May 2012.

Appendix 13: A Rejection of Standardisation

Among standardised approaches, grounded theory is influential (Bluff 2005). In its various forms grounded theory involves a three-level approach to coding (open, axial and selective) in which the researcher moves from identification of basic themes to systematic (“constant”) comparison of categories and eventually, to an emergent theory grounded in the data (Strauss & Corbin 1994; Bluff 2005). The desire to create a standardised, clear method of qualitative data collection and analysis is unsurprising—in line with positivism, the standardisation of methods increases the rigour of a research study, thereby increasing the validity of resulting theoretical insights. Furthermore, standardising an inherently confusing process may be a result of the pressure placed upon qualitative researchers to conform to traditional quantitative, positivistic standards of validity and method (Denzin & Lincoln 2000). While bias may be undesirable in positivistic research, the expectations of positivists need not carry over to other research under other paradigms. Indeed, the illusion of bias-free methods of qualitative research capable of studying social reality may prove harmful for other, less standardised yet entirely legitimate research paradigms.

Grounded theory seeks to eliminate bias or researcher assumptions in the development of emergent theory, which is purportedly accomplished through standardised data collection and analysis methods (Kelly 2010), yet the influence of the researcher (or the researcher’s hermeneutic circle) is central and unavoidable in comprehending social reality under interpretivist (e.g. hermeneutic and social constructionist) paradigms (Schwandt 2000; Patterson & Williams 2002; Urquhart & Fernández 2006). Socially constructed knowledge is separated by grounded theory into first and second order concepts to demonstrate its elimination of researcher influence: first order concepts are the interpretations of practitioners, while second order concepts are the researcher’s “interpretations of interpretations” (Maanen 1979, p.541). Grounded theory claims to provide a standardised method of “assembling and sorting first order concepts by looking for patterns and saturation” (Jones & Alony 2011, p.97). By limiting itself to knowledge socially constructed through interpretation by practitioners rather than researchers, grounded theory claims to reduce the influence of researcher bias and interpretation.

There is reason to doubt claims to this effect. Proponents have recognised the practical difficulties of divorcing oneself from the “accumulations of knowledge and experience which

temper understanding, observation and interpretation” (Jones & Alony 2011, p.102). Such difficulties are unsurprising from the perspective of hermeneutics, as it is impossible to divorce oneself entirely from one’s hermeneutic circle. In collecting empirical data researchers necessarily interpret the beliefs of participants, whether or not they are aware of it. In this sense the act of interpretation is second-nature and dependent upon the researcher’s hermeneutic circle (Gadamer 2004).

The separation into first and second order concepts is untenable. If “social reality” does not exist separately or externally from the people that create it, then the elimination of bias is impossible because social reality can only be comprehended through participation (or interpretation), which is necessarily biased by the hermeneutic circle of the interpreter. Each interpreter therefore creates a personal interpretation of social reality. This implies that the ordering of social reality is untenable because first order concepts cannot be objectively transferred to others. Rather, all concepts are given content or “constructed” by the interpreter during the act of interpretation. A construction of a concept is therefore personal to the interpreter that created it, and cannot be shared between participants in social reality without being re-interpreted or re-constructed within a new perspective. If this is true, all we are left with is an ever increasing chain of second order ‘interpretations of interpretations’.

An iterative relationship between empirical data, ethical theory and the interpretation of the researcher is central to this project’s methodology (See: Chapters 6 and 7). Iteration is ‘messy’ by definition, as the influence of each component of analysis in the process of refinement and interpretation is not always clear, even to the researcher performing the analysis. The researcher’s hermeneutic circle which shapes interpretation and analysis is imperfectly grasped by the researcher himself, meaning absolute clarity and standardisation of analytical methods in interpretive (or hermeneutic) qualitative research is impossible. While a clear description of the researcher’s biases and background can contribute to rigour of a qualitative research project (Mays & Pope 1995), such an account is always imperfect due to the researcher’s imperfect understanding of the influences on his interpretation.

Standardisation relies not only on standardised methods of coding, categorisation and connecting strategies (Maxwell 1998), but on common validity criteria as well (Mays & Pope 1995; Bluff 2005). The concept of data saturation is central to the validity of the theory developed in grounded theory, as the search for negative evidence is seen to justify

generalisations beyond the study's sample (Bluff 2005; Jones & Alony 2011). In this project, interpretations, categories and themes identified in the analysis, while being iteratively introduced into interviews as the study progressed, were not used as a test for data saturation. Adding further participants to this sample will increase the scope of the moral beliefs and implications considered, but will not prove that the resulting theoretical insights are any more legitimate or generalisable without further supporting arguments.

Any interpretation of social reality is and will necessarily remain incomplete (Patterson & Williams 2002); standardisation of methods does not change this reality. Standardisation should therefore be rejected, otherwise in the pursuit of generalisability and validity the researcher risks losing sight of the "unusual, the serendipitous—the puzzle" whose solving provides unforeseeable insights into the phenomenon (Marshall & Rossman 1999, p.151). Therefore, the critical refinement of the researcher and participants' interpretations in hermeneutic dialogue is enough to fulfil the standards of quality outlined in Chapter 6; there is no need to hide behind dubious standards of validity and standardised methods of data analysis.

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Appendix 14: Empirical Study Recruitment Documents

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A14.1 Consent Sheet – Dementia Carers



An Investigation into Ethical Issues of Personal Health Monitoring Participant Consent Form

Issue	Respondent's initial
I have read the information presented in the Participant Information Sheet (Version 1.0 – 30.01.2013 – Patients – Dementia Carers) about the study "An Investigation into Ethical Issues of Personal Health Monitoring."	
I have had the opportunity to ask any questions related to this study, and received satisfactory answers to my questions, and any additional details I wanted.	
I am aware that anonymised excerpts and quotations from the interview may be included in publications to come from this research and used in future interviews.	
I give permission for the interview to be recorded using audio recording equipment.	
I understand that relevant sections of the data collected during the study may be looked at by individuals from De Montfort University and regulatory authorities. I give permission for these individuals to have access to data from this study.	
I understand that I may withdraw my consent at any time by advising the researcher.	

With full knowledge of all foregoing, I agree to participate in this study.

I agree to being contacted in the future by the researchers if my responses give rise to interesting findings or require clarification:

☐ No ☐ Yes

I wish to be notified when results of the study are made publicly available:

☐ No ☐ Yes

If yes to either of the above, my preferred method of being contacted is:

☐ Telephone

☐ Email

Participant		Consent	
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Version 1.0

30.01.2012

Patients – Dementia Carers

To be used in conjunction with Participant Information Sheet (Version 1.0 – 30.01.2013 – Patients – Dementia Carers)

Trust Headquarters, Level 3, Balmoral Building, Leicester Royal Infirmary, Leicester LE1 5WW

Website: www.uhl-tr.nhs.uk

Chairman Mr Martin Hindle Chief Executive Mr Malcolm Lowe-Lauri

Name:		taken by	
Participant Signature:		Signature	
Date		Date	

A14.2 Consent Sheet – Diabetes



University Hospitals of Leicester



NHS Trust

Leicester General Hospital

Gwendolen Road

Leicester

LE5 4PW

Tel: 0300 303 1573

Switchboard Fax: 0116 258 7565

Minicom: 0116 287 9852

An Investigation into Ethical Issues of Personal Health Monitoring Participant Consent Form

Issue	Respondent's initial
I have read the information presented in the Participant Information Sheet (Version 4.0 – 25.05.2012 – Patients – Diabetes) about the study "An Investigation into Ethical Issues of Personal Health Monitoring."	
I have had the opportunity to ask any questions related to this study, and received satisfactory answers to my questions, and any additional details I wanted.	
I am aware that anonymised excerpts and quotations from the interview may be included in publications to come from this research and used in future interviews.	
I give permission for the interview to be recorded using audio recording equipment.	
I understand that relevant sections of the data collected during the study may be looked at by individuals from De Montfort University and regulatory authorities. I give permission for these individuals to have access to data from this study.	
I understand that I may withdraw my consent at any time by advising the researcher.	

With full knowledge of all foregoing, I agree to participate in this study.

I agree to being contacted in the future by the researchers if my responses give rise to interesting findings or require clarification:

☐ No ☐ Yes

I wish to be notified when results of the study are made publicly available:

☐ No ☐ Yes

Version 4.0

25.05.2012

Patients – Diabetes

To be used in conjunction with Participant Information Sheet (Version 4.0 – 25.05.2012 – Patients – Diabetes)

Trust Headquarters, Level 3, Balmoral Building, Leicester Royal Infirmary, Leicester LE1 5WW

Website: www.uhl-tr.nhs.uk

Chairman Mr Martin Hindle Chief Executive Mr Malcolm Lowe-Lauri

If yes to either of the above, my preferred method of being contacted is:

☐ Telephone

☐ Email

Participant Name:		Consent taken by	
Participant Signature:		Signature	
Date		Date	

A14.3 Consent Sheet – Hypertension



University Hospitals of Leicester **NHS**
NHS Trust

Leicester General Hospital
Gwendolen Road
Leicester
LE5 4PW

Tel: 0300 303 1573
Switchboard Fax: 0116 258 7565
Minicom: 0116 287 9852

An Investigation into Ethical Issues of Personal Health Monitoring Participant Consent Form

Issue	Respondent's initial
I have read the information presented in the Participant Information Sheet (Version 4.0 – 25.05.2012 – Patients – Hypertension) about the study "An Investigation into Ethical Issues of Personal Health Monitoring."	
I have had the opportunity to ask any questions related to this study, and received satisfactory answers to my questions, and any additional details I wanted.	
I am aware that anonymised excerpts and quotations from the interview may be included in publications to come from this research and used in future interviews.	
I give permission for the interview to be recorded using audio recording equipment.	
I understand that relevant sections of the data collected during the study may be looked at by individuals from De Montfort University and regulatory authorities. I give permission for these individuals to have access to data from this study.	
I understand that I may withdraw my consent at any time by advising the researcher.	

With full knowledge of all foregoing, I agree to participate in this study.

I agree to being contacted in the future by the researchers if my responses give rise to interesting findings or require clarification:

☐ No ☐ Yes

I wish to be notified when results of the study are made publicly available:

☐ No ☐ Yes

Version 4.0

25.05.2012

Patients – Hypertension

To be used in conjunction with Participant Information Sheet (Version 4.0 – 25.05.2012 – Patients - Hypertension)

Trust Headquarters, Level 3, Balmoral Building, Leicester Royal Infirmary, Leicester LE1 5WW
Website: www.uhl-tr.nhs.uk

Chairman Mr Martin Hindle Chief Executive Mr Malcolm Lowe-Lauri

If yes to either of the above, my preferred method of being contacted is:

☐ Telephone

☐ Email

Participant Name:		Consent taken by	
Participant Signature:		Signature	
Date		Date	

A14.4 Consent Sheet – Disease Specialist - Diabetes



University Hospitals of Leicester **NHS**
NHS Trust

Leicester General Hospital
Gwendolen Road
Leicester
LE5 4PW

Tel: 0300 303 1573
Switchboard Fax: 0116 258 7565
Minicom: 0116 287 9852

An Investigation into Ethical Issues of Personal Health Monitoring

Participant Consent Form

Issue	Respondent's initial
I have read the information presented in the information sheet (Version 3.0 – 07.03.2012 – Disease Specialist - Diabetes) about the study "An Investigation into Ethical Issues of Personal Health Monitoring."	
I have had the opportunity to ask any questions related to this study, and received satisfactory answers to my questions, and any additional details I wanted.	
I am aware that anonymised excerpts and quotations from the interview may be included in publications to come from this research and used in future interviews.	
I give permission for the interview to be recorded using audio recording equipment.	
I understand that relevant sections of the data collected during the study may be looked at by individuals from De Montfort University and regulatory authorities. I give permission for these individuals to have access to data from this study.	
I understand that I may withdraw my consent at any time by advising the researcher.	

With full knowledge of all foregoing, I agree to participate in this study.

I agree to being contacted in the future by the researchers if my responses give rise to interesting findings or require clarification:

☐ No ☐ Yes

I wish to be notified when results of the study are made publicly available:

☐ No ☐ Yes

Version 3.0

07.03.2012

Disease Specialist - Diabetes

To be used in conjunction with Participant Information Sheet (Version 3.0 - 07.03.2012 – Disease Specialist - Diabetes)

1

Trust Headquarters, Level 3, Balmoral Building, Leicester Royal Infirmary, Leicester LE1 5WW

Website: www.uhl-tr.nhs.uk

Chairman Mr Martin Hindle Chief Executive Mr Malcolm Lowe-Lauri

If yes to either of the above, my preferred method of being contacted is:

☐ Telephone

☐ Email

Participant Name:		Consent taken by	
Participant Signature:		Signature	
Date		Date	

A14.5 Consent Sheet – Disease Specialist - Hypertension



University Hospitals of Leicester **NHS**
NHS Trust

Leicester General Hospital
Gwendolen Road
Leicester
LE5 4PW

Tel: 0300 303 1573
Switchboard Fax: 0116 258 7565
Minicom: 0116 287 9852

An Investigation into Ethical Issues of Personal Health Monitoring

Participant Consent Form

Issue	Respondent's initial
I have read the information presented in the information sheet (Version 3.0 – 07.03.2012 – Disease Specialist - Hypertension) about the study "An Investigation into Ethical Issues of Personal Health Monitoring."	
I have had the opportunity to ask any questions related to this study, and received satisfactory answers to my questions, and any additional details I wanted.	
I am aware that anonymised excerpts and quotations from the interview may be included in publications to come from this research and used in future interviews.	
I give permission for the interview to be recorded using audio recording equipment.	
I understand that relevant sections of the data collected during the study may be looked at by individuals from De Montfort University and regulatory authorities. I give permission for these individuals to have access to data from this study.	
I understand that I may withdraw my consent at any time by advising the researcher.	

With full knowledge of all foregoing, I agree to participate in this study.

I agree to being contacted in the future by the researchers if my responses give rise to interesting findings or require clarification:

☐ No ☐ Yes

I wish to be notified when results of the study are made publicly available:

☐ No ☐ Yes

Version 3.0

07.03.2012

Disease Specialist - Hypertension

To be used in conjunction with Participant Information Sheet (Version 3.0 - 07.03.2012 – Disease Specialist - Hypertension)

1

Trust Headquarters, Level 3, Balmoral Building, Leicester Royal Infirmary, Leicester LE1 5WW

Website: www.uhl-tr.nhs.uk

Chairman Mr Martin Hindle Chief Executive Mr Malcolm Lowe-Lauri

If yes to either of the above, my preferred method of being contacted is:

☐ Telephone

☐ Email

Participant Name:		Consent taken by	
Participant Signature:		Signature	
Date		Date	



An Investigation into Ethical Issues of Personal Health Monitoring

Participant Consent Form

Issue	Respondent's initial
I have read the information presented in the information sheet (Version 3.0 – 07.03.2012 – Service Officers - Dementia) about the study "An Investigation into Ethical Issues of Personal Health Monitoring."	
I have had the opportunity to ask any questions related to this study, and received satisfactory answers to my questions, and any additional details I wanted.	
I am aware that anonymised excerpts and quotations from the interview may be included in publications to come from this research and used in future interviews.	
I give permission for the interview to be recorded using audio recording equipment.	
I understand that relevant sections of the data collected during the study may be looked at by individuals from De Montfort University and regulatory authorities. I give permission for these individuals to have access to data from this study.	
I understand that I may withdraw my consent at any time by advising the researcher.	

With full knowledge of all foregoing, I agree to participate in this study.

I agree to being contacted in the future by the researchers if my responses give rise to interesting findings or require clarification:

☐ No ☐ Yes

I wish to be notified when results of the study are made publicly available:

☐ No ☐ Yes

If yes to either of the above, my preferred method of being contacted is:

☐ Telephone

☐ Email

Version 3.0

07.03.2012

Service Officers - Dementia

To be used in conjunction with Participant Information Sheet (Version 3.0 - 07.03.2012 – Service Officers - Dementia)

Participant Name:		Consent taken by	
Participant Signature:		Signature	
Date		Date	

A14.7 Consent Sheet – Care Commissioners



University Hospitals of Leicester



NHS Trust

Leicester General Hospital

Gwendolen Road

Leicester

LE5 4PW

Tel: 0300 303 1573

Switchboard Fax: 0116 258 7565

Minicom: 0116 287 9852

An Investigation into Ethical Issues of Personal Health Monitoring

Participant Consent Form

Issue	Respondent's initial
I have read the information presented in the information sheet (Version 3.0 – 07.03.2012 – NHS Managers Care Commissioners) about the study "An Investigation into Ethical Issues of Personal Health Monitoring."	
I have had the opportunity to ask any questions related to this study, and received satisfactory answers to my questions, and any additional details I wanted.	
I am aware that anonymised excerpts and quotations from the interview may be included in publications to come from this research and used in future interviews.	
I give permission for the interview to be recorded using audio recording equipment.	
I understand that relevant sections of the data collected during the study may be looked at by individuals from De Montfort University and regulatory authorities. I give permission for these individuals to have access to data from this study.	
I understand that I may withdraw my consent at any time by advising the researcher.	

With full knowledge of all foregoing, I agree to participate in this study.

I agree to being contacted in the future by the researchers if my responses give rise to interesting findings or require clarification:

☐ No ☐ Yes

I wish to be notified when results of the study are made publicly available:

Version 3.0

07.03.2012

NHS Managers – Care Commissioners

To be used in conjunction with Participant Information Sheet (Version 3.0 – 07.03.2012 – NHS Managers Care Commissioners)

1

Trust Headquarters, Level 3, Balmoral Building, Leicester Royal Infirmary, Leicester LE1 5WW

Website: www.uhl-tr.nhs.uk

Chairman Mr Martin Hindle Chief Executive Mr Malcolm Lowe-Lauri

☐ No ☐ Yes

If yes to either of the above, my preferred method of being contacted is:

☐ Telephone

☐ Email

Participant Name:		Consent taken by	
Participant Signature:		Signature	
Date		Date	



An Investigation into Ethical Issues of Personal Health Monitoring Participant Information Sheet

Thank you for taking the time to read this paper.

You are being invited to take part in a research study conducted by De Montfort University. Participation in the study is entirely voluntary and will not affect your medical care in any way.

The study will involve being interviewed by a researcher from De Montfort University about your experiences caring for someone with dementia. By interviewing you we hope to understand your points of view on any advantages and potential disadvantages raised by health monitoring technologies. We may ask you questions such as:

- Are you willing to use health monitoring at home as part of your caring? If not, why?
- How would it affect your relationships with family and friends?

If you are chosen by the researchers to participate in the study, you will be contacted by telephone or e-mail, and may contact you again if we have not heard back from you within two weeks. We may also contact you a few months after completion of the study to ask for clarification, but you do not have to talk to us again.

This study is being undertaken for educational purposes, as part of a PhD in Computer Ethics at De Montfort University.

Your Role as a Participant

We would like to ask you to share your views and opinions about Personal Health Monitoring devices. If you are willing to help we would like to spend 30-45 minutes talking with you at a time and location convenient for you. This is an informal conversation and you can choose to not answer any of the questions asked, especially if you find a question embarrassing, sensitive or otherwise upsetting. We may also ask to talk to you a second time, which obviously you are free to decline. With your permission, both interviews will

Version 1.0

30.01.2013

Patients – Dementia Carers

Trust Headquarters, Level 3, Balmoral Building, Leicester Royal Infirmary, Leicester LE1 5WW
Website: www.uhl-tr.nhs.uk
Chairman Mr Martin Hindle Chief Executive Mr Malcolm Lowe-Lauri

be recorded on an audio device.

We may also ask for details about the doctor or specialist you see most often for management of your condition so that we may interview them. You **do not** have to provide us with this information. However, if you do, we will **not** tell your doctor about your participation in the study.

Before we talk to you we will ask you to sign a consent form but **you may withdraw from the study at any time** for any reason and no further questions will be asked. If you wish to withdraw you can tell the researcher talking to you or contact the lead researcher (Brent Mittelstadt) at bmittelstadt@dmu.ac.uk or 0750 712 1631. If you withdraw from the study all personal data we have collected from you will be destroyed.

Confidentiality

Any information you provide will be treated as confidential, your name, address and any other personal information will not appear in any publications from this study and will only be available to the research team and De Montfort University examiners. All personal information and interview data will be kept in a locked cabinet or on a password protected university computer. Anonymous quotes may be used in publications and other interviews.

The research team requests that you do not reveal information about criminal activity or medical malpractice during the study, as there may be a duty of disclosure that would require the researchers to breach confidentiality.

The data you provide for this study will not be used for any purposes other than research.

Risks and Benefits

There are no anticipated risks for you if you participate in this study. By participating you may benefit from thinking about potential changes in medical care and any policy and organisational decisions resulting from the study. Results from this study may be used in the future to improve the

quality of medical care available in the UK.

Who has reviewed the study?

This study has been favourably reviewed by the De Montfort University Human Research Ethics Committee. De Montfort University's lone worker policy (ref: SP3/57/96) applies to this study.

Questions and Complaints

In the event that you wish to make a complaint about any aspect of the study, we encourage you to contact the Chief Investigator at the contact details below. Alternatively, you may contact the study's coordinator (Jan Hewitt) at 0116 250 6284, or by post at:

Jan Hewitt
Graduate School Office
Room 1.06, John Whitehead Building
De Montfort University
The Gateway
Leicester LE1 9BH

How to Participate

To indicate your interest in participating in the study, or to request further information or answers to any questions you may have, please contact the Chief Investigator at the contact details below. Alternatively, fill in the detachable form on the provided Participant Invitation Letter and hand it back to the person that provided you with this pack. We look forward to hearing from you!

Yours faithfully,



Brent Mittelstadt
Chief Investigator
De Montfort University
Centre for Computing and Social Responsibility
The Gateway
Leicester LE1 9BH, UK
Tel.: + 44 750 712 1631
E-mail: bmittelstadt@dmu.ac.uk



University Hospitals of Leicester



NHS Trust

Leicester General Hospital

Gwendolen Road

Leicester

LE5 4PW

Tel: 0300 303 1573

Switchboard Fax: 0116 258 7565

Minicom: 0116 287 9852

An Investigation into Ethical Issues of Personal Health Monitoring Participant Information Sheet

Thank you for taking the time to read this paper.

You are being invited to take part in a research study conducted by De Montfort University. Participation in the study is entirely voluntary and will not affect your medical care in any way.

The study will involve being interviewed by a researcher from De Montfort University about your experiences with diabetes. By interviewing you we hope to understand your points of view on any advantages and potential disadvantages raised by health monitoring technologies. We may ask you questions such as:

- Are you willing to use health monitoring at home? If not, why?
- How would it affect your relationships with family, friends and your GP?

If you are chosen by the researchers to participate in the study, you will be contacted by telephone or e-mail, and may contact you again if we have not heard back from you within two weeks. We may also contact you a few months after completion of the study to ask for clarification, but you do not have to talk to us again.

This study is being undertaken for educational purposes, as part of a PhD in Computer Ethics at De Montfort University.

Your Role as a Participant

We would like to ask you to share your views and opinions about Personal Health Monitoring devices. If you are willing to help we would like to spend 30-45 minutes talking with you at a time and location convenient for you.

Version 4.0

25.05.2012

Patients - Diabetes

Trust Headquarters, Level 3, Balmoral Building, Leicester Royal Infirmary, Leicester LE1 5WW

Website: www.uhl-tr.nhs.uk

Chairman Mr Martin Hindle Chief Executive Mr Malcolm Lowe-Lauri

This is an informal conversation and you can choose to not answer any of the questions asked, especially if you find a question embarrassing, sensitive or otherwise upsetting. We may also ask to talk to you a second time, which obviously you are free to decline. With your permission, both interviews will be recorded on an audio device.

We may also ask for details about the doctor or specialist you see most often for management of your condition so that we may interview them. You **do not** have to provide us with this information. However, if you do, we will **not** tell your doctor about your participation in the study.

Before we talk to you we will ask you to sign a consent form but **you may withdraw from the study at any time** for any reason and no further questions will be asked. If you wish to withdraw you can tell the researcher talking to you or contact the lead researcher (Brent Mittelstadt) at bmittelstadt@dmu.ac.uk or 0750 712 1631. If you withdraw from the study all personal data we have collected from you will be destroyed.

Confidentiality

Any information you provide will be treated as confidential, your name, address and any other personal information will not appear in any publications from this study and will only be available to the research team and De Montfort University examiners. All personal information and interview data will be kept in a locked cabinet or on a password protected university computer. Anonymous quotes may be used in publications and other interviews.

The research team requests that you do not reveal information about criminal activity or medical malpractice during the study, as there may be a duty of disclosure that would require the researchers to breach confidentiality.

The data you provide for this study will not be used for any purposes other than research.

Risks and Benefits

There are no anticipated risks for you if you participate in this study. By participating you may benefit from thinking about potential changes in medical care and any policy and organisational decisions resulting from the study. Results from this study may be used in the future to improve the quality of medical care available in the UK.

Who has reviewed the study?

This study has been favourably reviewed by the De Montfort University Human Research Ethics Committee and the Leicester NHS Research Ethics Committee. De Montfort University's lone worker policy (ref: SP3/57/96) applies to this study.

Questions and Complaints

In the event that you wish to make a complaint about any aspect of the study, we encourage you to contact the Chief Investigator at the contact details below. Alternatively, you may contact the study's coordinator (Jan Hewitt) at 0116 250 6284, or by post at:

Jan Hewitt
Graduate School Office
Room 1.06, John Whitehead Building
De Montfort University
The Gateway
Leicester LE1 9BH

How to Participate

To indicate your interest in participating in the study, or to request further information or answers to any questions you may have, please contact the Chief Investigator at the contact details below. Alternatively, fill in the detachable form on the provided Participant Invitation Letter and hand it back to the person that provided you with this pack. We look forward to hearing from you!

Yours faithfully,

A handwritten signature in black ink, appearing to read 'Brent Mittelstadt', with a stylized, flowing script.

Brent Mittelstadt
Chief Investigator
De Montfort University
Centre for Computing and Social Responsibility
The Gateway
Leicester LE1 9BH, UK
Tel.: + 44 750 712 1631
E-mail: bmittelstadt@dmu.ac.uk



University Hospitals of Leicester



NHS Trust

Leicester General Hospital

Gwendolen Road

Leicester

LE5 4PW

Tel: 0300 303 1573

Switchboard Fax: 0116 258 7565

Minicom: 0116 287 9852

An Investigation into Ethical Issues of Personal Health Monitoring Participant Information Sheet

Thank you for taking the time to read this paper.

You are being invited to take part in a research study conducted by De Montfort University. Participation in the study is entirely voluntary and will not affect your medical care in any way.

The study will involve being interviewed by a researcher from De Montfort University about your experiences with hypertension. By interviewing you we hope to understand your points of view on any advantages and potential disadvantages raised by health monitoring technologies. We may ask you questions such as:

- Are you willing to use health monitoring at home? If not, why?
- How would it affect your relationships with family, friends and your GP?

If you are chosen by the researchers to participate in the study, you will be contacted by telephone or e-mail, and may contact you again if we have not heard back from you within two weeks. We may also contact you a few months after completion of the study to ask for clarification, but you do not have to talk to us again.

This study is being undertaken for educational purposes, as part of a PhD in Computer Ethics at De Montfort University.

Your Role as a Participant

We would like to ask you to share your views and opinions about Personal Health Monitoring devices. If you are willing to help we would like to spend 30-45 minutes talking with you at a time and location convenient for you.

Version 4.0

25.05.2012

Patients - Hypertension

Trust Headquarters, Level 3, Balmoral Building, Leicester Royal Infirmary, Leicester LE1 5WW

Website: www.uhl-tr.nhs.uk

Chairman Mr Martin Hindle Chief Executive Mr Malcolm Lowe-Lauri

This is an informal conversation and you can choose to not answer any of the questions asked, especially if you find a question embarrassing, sensitive or otherwise upsetting. We may also ask to talk to you a second time, which obviously you are free to decline. With your permission, both interviews will be recorded on an audio device.

We may also ask for details about the doctor or specialist you see most often for management of your condition so that we may interview them. You **do not** have to provide us with this information. However, if you do, we will **not** tell your doctor about your participation in the study.

Before we talk to you we will ask you to sign a consent form but **you may withdraw from the study at any time** for any reason and no further questions will be asked. If you wish to withdraw you can tell the researcher talking to you or contact the lead researcher (Brent Mittelstadt) at bmittelstadt@dmu.ac.uk or 0750 712 1631. If you withdraw from the study all personal data we have collected from you will be destroyed.

Confidentiality

Any information you provide will be treated as confidential, your name, address and any other personal information will not appear in any publications from this study and will only be available to the research team and De Montfort University examiners. All personal information and interview data will be kept in a locked cabinet or on a password protected university computer. Anonymous quotes may be used in publications and other interviews.

The research team requests that you do not reveal information about criminal activity or medical malpractice during the study, as there may be a duty of disclosure that would require the researchers to breach confidentiality.

The data you provide for this study will not be used for any purposes other than research.

Risks and Benefits

There are no anticipated risks for you if you participate in this study. By participating you may benefit from thinking about potential changes in medical care and any policy and organisational decisions resulting from the study. Results from this study may be used in the future to improve the quality of medical care available in the UK.

Who has reviewed the study?

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In the event that you wish to make a complaint about any aspect of the study, we encourage you to contact the Chief Investigator at the contact details below. Alternatively, you may contact the study's coordinator (Jan Hewitt) at 0116 250 6284, or by post at:

Jan Hewitt
Graduate School Office
Room 1.06, John Whitehead Building
De Montfort University
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Leicester LE1 9BH

How to Participate

To indicate your interest in participating in the study, or to request further information or answers to any questions you may have, please contact the Chief Investigator at the contact details below. Alternatively, fill in the detachable form on the provided Participant Invitation Letter and hand it back to the person that provided you with this pack. We look forward to hearing from you!

Yours faithfully,



Brent Mittelstadt
Chief Investigator
De Montfort University
Centre for Computing and Social Responsibility
The Gateway
Leicester LE1 9BH, UK
Tel.: + 44 750 712 1631
E-mail: bmittelstadt@dmu.ac.uk



University Hospitals of Leicester **NHS**
NHS Trust

Leicester General Hospital
Gwendolen Road
Leicester
LE5 4PW
Tel: 0300 303 1573
Switchboard Fax: 0116 258 7565
Minicom: 0116 287 9852

An Investigation into Ethical Issues of Personal Health Monitoring

Local Collaborator Information Sheet

Dear <insert name>,

We would like to ask you to participate in a study conducted by De Montfort University on the ethical issues raised by Personal Health Monitoring (PHM) systems.

We hope better to understand the ethical implications of PHM through interviewing patients with diabetes. We plan to ask them questions such as:

- Are you willing to use health monitoring at home? If not, why?
- What would prevent you from using PHM? What risks or problems would it raise?
- How would it affect your relationships with family and medical personnel?

We are asking for your help in recruiting patients with diabetes to the study. Recruitment can proceed in the method(s) most convenient for you. We propose the following two recruitment methods, although we are open to other methods according to your requirements:

- Distribution of invitation packets to patients under your care by you during your normal work routines.
- Distribution of invitation packets at your outpatient services (if available) by the Chief Investigator.

Participation in the study is entirely voluntary and will involve one to two interviews of 30-45 minutes to take place at a location convenient for the patient. Participants can decline to answer any questions and withdraw at any time, at which point all identifiable data collected about them would be destroyed. Prior to participating in the study and the patient's role will be verbally reviewed with them. They will then have the opportunity to ask questions, and informed consent will be taken in writing.

The study is using a theoretical sampling method, meaning we may ask you to distribute invitation packets to patients meeting certain requirements (e.g. demographics, prior experience with health monitoring, attitude towards health technology, etc). The profile of the required participant will evolve throughout the study based on the analysis of interview data and be communicated to you as it changes, until theoretical saturation is reached. We anticipate requiring 5-10 people with diabetes for the study.

The research team will never require or ask for access to patient records or the names of potential participants. Instead, invitation packets will direct potential participants to contact the Chief

Version 3.0

07.03.2012

Information Sheet - Disease Specialist - Diabetes

Trust Headquarters, Level 3, Balmoral Building, Leicester Royal Infirmary, Leicester LE1 5WW
Website: www.uhl-tr.nhs.uk
Chairman Mr Martin Hindle Chief Executive Mr Malcolm Lowe-Lauri

Investigator. We are therefore asking you to only distribute packets to patients that match the current profile of required participants. All participants should be capable of being interviewed and giving informed consent. The ability to give informed consent will be re-assessed by the Chief Investigator at the time of each interview.

The information provided by participants is confidential, except that with their permission anonymised quotes may be used in publications in international conferences and academic journals. Their name, contact details and any other personal identifying information will not appear in any publications resulting from this study and will only be available to the research team and De Montfort University examiners.

The information gained from the interview will only be used for the above objectives and will not be used for any other purpose or recorded in excess of what is required for the study.

There are no known or anticipated risks to you or your patients for participating in this study. By participating you and your patients may benefit from reflecting on questions about medical care and ethics, as well as from any policy and organisational decisions resulting from the study.

This study is being undertaken for educational purposes, as part of a doctoral degree at De Montfort University and has been favourably reviewed by the University's Human Research Ethics Committee and the Leicester NHS Research Ethics Committee.

If you have any questions regarding this study or would like additional information please ask the lead researcher or interviewer at any time.

Yours faithfully,

Brent Mittelstadt
Chief Investigator
De Montfort University
Centre for Computing and Social Responsibility
The Gateway, Leicester LE1 9BH, UK
Tel.: +44 750 712 1631
E-mail: bmittelstadt@dmu.ac.uk



University Hospitals of Leicester



NHS Trust

Leicester General Hospital

Gwendolen Road

Leicester

LE5 4PW

Tel: 0300 303 1573

Switchboard Fax: 0116 258 7565

Minicom: 0116 287 9852

An Investigation into Ethical Issues of Personal Health Monitoring

Local Collaborator Information Sheet

Dear <insert name>,

We would like to ask you to participate in a study conducted by De Montfort University on the ethical issues raised by Personal Health Monitoring (PHM) systems.

We hope better to understand the ethical implications of PHM through interviewing patients with hypertension. We plan to ask them questions such as:

- Are you willing to use health monitoring at home? If not, why?
- What would prevent you from using PHM? What risks or problems would it raise?
- How would it affect your relationships with family and medical personnel?

We are asking for your help in recruiting patients with hypertension to the study. Recruitment can proceed in the method(s) most convenient for you. We propose the following two recruitment methods, although we are open to other methods according to your requirements:

- Distribution of invitation packets to patients under your care by you during your normal work routines.
- Distribution of invitation packets at your outpatient services (if available) by the Chief Investigator.

Participation in the study is entirely voluntary and will involve one to two interviews of 30-45 minutes to take place at a location convenient for the patient. Participants can decline to answer any questions and withdraw at any time, at which point all identifiable data collected about them would be destroyed. Prior to participating in the study and the patient's role will be verbally reviewed with them. They will then have the opportunity to ask questions, and informed consent will be taken in writing.

The study is using a theoretical sampling method, meaning we may ask you to distribute invitation packets to patients meeting certain requirements (e.g. demographics, prior experience with health monitoring, attitude towards health technology, etc). The profile of the required participant will evolve throughout the study based on the analysis of interview data and be communicated to you as it changes, until theoretical saturation is reached. We anticipate requiring 5-10 people with hypertension for the study.

The research team will never require or ask for access to patient records or the names of potential participants. Instead, invitation packets will direct potential participants to contact the Chief

Version 3.0

07.03.2012

Information Sheet - Disease Specialist - Hypertension

Trust Headquarters, Level 3, Balmoral Building, Leicester Royal Infirmary, Leicester LE1 5WW

Website: www.uhl-tr.nhs.uk

Chairman Mr Martin Hindle Chief Executive Mr Malcolm Lowe-Lauri

Investigator. We are therefore asking you to only distribute packets to patients that match the current profile of required participants. All participants should be capable of being interviewed and giving informed consent. The ability to give informed consent will be re-assessed by the Chief Investigator at the time of each interview.

The information provided by participants is confidential, except that with their permission anonymised quotes may be used in publications in international conferences and academic journals. Their name, contact details and any other personal identifying information will not appear in any publications resulting from this study and will only be available to the research team and De Montfort University examiners.

The information gained from the interview will only be used for the above objectives and will not be used for any other purpose or recorded in excess of what is required for the study.

There are no known or anticipated risks to you or your patients for participating in this study. By participating you and your patients may benefit from reflecting on questions about medical care and ethics, as well as from any policy and organisational decisions resulting from the study.

This study is being undertaken for educational purposes, as part of a doctoral degree at De Montfort University and has been favourably reviewed by the University's Human Research Ethics Committee and the Leicester NHS Research Ethics Committee.

If you have any questions regarding this study or would like additional information please ask the lead researcher or interviewer at any time.

Yours faithfully,

Brent Mittelstadt
Chief Investigator
De Montfort University
Centre for Computing and Social Responsibility
The Gateway, Leicester LE1 9BH, UK
Tel.: +44 750 712 1631
E-mail: bmittelstadt@dmu.ac.uk



An Investigation into Ethical Issues of Personal Health Monitoring Participant Information Sheet

Dear <insert name>,

We would like to ask you to participate in a study conducted by De Montfort University on the ethical issues raised by Personal Health Monitoring (PHM) systems. You have been asked to participate on the basis that the carer for one of your patients with dementia is also participating in the study.

We hope better to understand the ethical implications of PHM through questions such as:

- How would PHM affect your relationships with patients and the NHS?
- How would you use PHM in your practice?
- What human “goods” or values are affected by PHM?

Participation in this study is entirely voluntary. It will involve one to two interviews of 30-45 minutes to take place at a location convenient for you. Prior to participating the study and your role in it will be reviewed with you, you will have the opportunity to ask questions, and your consent will be taken.

You may decline to answer any of the interview questions. You may also decide to withdraw from this study at any time by advising the interviewer or by contacting the lead researcher at bmittelstadt@dmu.ac.uk or 0750 712 1631. If you notify us of your withdrawal, all identifiable data will be destroyed.

The information you provide is confidential, except that with your permission anonymised quotes may be used in publications in international conferences and academic journals. Your name, job title and any other personal identifying information will not appear in any publications resulting from this study and will only be available to the research team and De Montfort University examiners.

The information gained from the interview will only be used for the above objectives and will not be used for any other purpose or recorded in excess of what is required for the study.

There are no known or anticipated risks to you as a participant in this study. By participating you may benefit from reflecting on questions about medical care and ethics, as well as from any policy and organisational decisions resulting from the study.

The research team requests that you do not reveal information about criminal activity or medical malpractice during the study, as such disclosures must be reported to the appropriate authorities. However, disclosures of malpractice will only be reported with your consent.

This study is being undertaken for educational purposes, as part of a doctoral degree at De Montfort University and has been favourably reviewed by the University's Human Research Ethics Committee and the Leicester NHS Research Ethics Committee.

If you have any questions regarding this study or would like additional information please ask the lead researcher or interviewer at any time.

Yours faithfully,

Brent Mittelstadt
Chief Investigator
De Montfort University
Centre for Computing and Social Responsibility
The Gateway, Leicester LE1 9BH, UK
Tel.: + 44 750 712 1631
E-mail: bmittelstadt@dmu.ac.uk



University Hospitals of Leicester



NHS Trust

Leicester General Hospital

Gwendolen Road

Leicester

LE5 4PW

Tel: 0300 303 1573

Switchboard Fax: 0116 258 7565

Minicom: 0116 287 9852

An Investigation into Ethical Issues of Personal Health Monitoring Participant Information Sheet

Dear Participant

We would like to ask you to participate in a study conducted by De Montfort University on the ethical issues raised by Personal Health Monitoring (PHM) systems. You have been asked to participate on the basis that you are responsible for commissioning health services for the Leicestershire Partnership NHS Trust.

We hope better to understand the ethical implications of PHM through questions such as:

- How would data gathered by PHM devices be useful for the NHS?
- How would you encourage doctors and patients to use PHM?
- What role do resource considerations play in commissioning?
- What human “goods” or values are affected by PHM?

Participation in this study is entirely voluntary. It will involve one to two interviews of 30-45 minutes to take place at a location convenient for you. Prior to participating the study and your role in it will be reviewed with you, you will have the opportunity to ask questions, and your consent will be taken.

You may decline to answer any of the interview questions. You may also decide to withdraw from this study at any time by advising the interviewer or by contacting the lead researcher at bmittelstadt@dmu.ac.uk or 0750 712 1631. If you notify us of your withdrawal, all identifiable data will be destroyed.

The information you provide is confidential, except that with your permission anonymised quotes may be used in publications in international conferences and academic journals. Your name, job title and any other personal identifying information will not appear in any publications resulting from this study and will only be available to the research team and De Montfort University examiners.

The information gained from the interview will only be used for the above objectives and will not be used for any other purpose or recorded in excess of what is required for the study.

There are no known or anticipated risks to you as a participant in this study. By participating you may benefit from reflecting on questions about medical care and ethics, as well as from any policy and organisational decisions resulting from the study.

The research team requests that you do not reveal information about criminal activity or medical malpractice during the study, as such disclosures must be reported to the appropriate authorities. However, disclosures of malpractice will only be reported with your consent.

Version 3.0

07.03.2012 NHS Managers – Care Commissioners

Trust Headquarters, Level 3, Balmoral Building, Leicester Royal Infirmary, Leicester LE1 5WW

Website: www.uhl-tr.nhs.uk

Chairman Mr Martin Hindle Chief Executive Mr Malcolm Lowe-Lauri

This study is being undertaken for educational purposes, as part of a doctoral degree at De Montfort University and has been favourably reviewed by the University's Human Research Ethics Committee and the Leicester NHS Research Ethics Committee. If you have any questions regarding this study or would like additional information please ask the lead researcher or interviewer at any time.

Yours faithfully,

Brent Mittelstadt
Chief Investigator
De Montfort University
Centre for Computing and Social Responsibility
The Gateway, Leicester LE1 9BH, UK
Tel.: + 44 750 712 1631
E-mail: bmittelstadt@dmu.ac.uk



**An Investigation into Ethical Issues of Personal Health Monitoring
Invitation Letter**

Dear Sir or Madam,

You are invited to participate in a research study on dementia care being conducted by De Montfort University. The study is looking into ethical issues of newly developed medical monitoring or "Personal Health Monitoring" devices. **Participation in the study is entirely voluntary and does NOT involve testing of any medication, medical devices or therapies.**

If you are willing to help you will be asked to participate in up to two interviews lasting approximately 30-45 minutes each at a time and place convenient for you. The included Information Sheet will explain the study and your role in further detail. Please read the included Information Sheet before deciding if you would like to participate in the study. If you would like to participate or want more information please contact the research team using the details below.

Yours faithfully,

A handwritten signature in black ink, appearing to read "Brent Mittelstadt".

Brent Mittelstadt

For more information or to indicate your interest in participating contact:

Brent Mittelstadt (Chief Investigator)

0750 712 1631

bmittelstadt@dmu.ac.uk

Alternatively, return this sheet to the person who gave you it (turn page over).

Please contact me regarding participation in the "An Investigation into the Ethical issues of Personal Health Monitoring" study:

Name _____ Phone _____

E-mail _____


Version 1.0

30.01.2012

Patients – Dementia Carer

Trust Headquarters, Level 3, Balmoral Building, Leicester Royal Infirmary, Leicester LE1 5WW
Website: www.uhl-tr.nhs.uk
Chairman Mr Martin Hindle Chief Executive Mr Malcolm Lowe-Lauri



University Hospitals of Leicester 
NHS Trust

Leicester General Hospital
Gwendolen Road
Leicester
LE5 4PW

Tel: 0300 303 1573
Switchboard Fax: 0116 258 7565
Minicom: 0116 287 9852

**An Investigation into Ethical Issues of Personal Health Monitoring
Invitation Letter**

Dear Sir or Madam,

You are invited to participate in a research study on diabetes being conducted by De Montfort University. The study is looking into ethical issues of newly developed medical monitoring or "Personal Health Monitoring" devices.

Participation in the study is entirely voluntary and does NOT involve testing of any medication, medical devices or therapies.

If you are willing to help you will be asked to participate in up to two interviews lasting approximately 30-45 minutes each at a time and place convenient for you. The included Information Sheet will explain the study and your role in further detail. Please read the included Information and Consent Sheets before deciding if you would like to participate in the study. If you would like to participate or want more information please contact the research team using the details below.

Yours faithfully,

A handwritten signature in black ink, appearing to read 'Brent Mittelstadt', written in a cursive style.

Brent Mittelstadt

For more information or to indicate your interest in participating contact:

Brent Mittelstadt (Chief Investigator)

0750 712 1631

bmittelstadt@dmu.ac.uk

Alternatively, return the detachable sheet to the person who gave it to you:

Please contact me regarding participation in the "An Investigation into the Ethical issues of Personal Health Monitoring" study:

Name _____ Phone _____

E-mail _____



University Hospitals of Leicester



NHS Trust

Leicester General Hospital

Gwendolen Road

Leicester

LE5 4PW

Tel: 0300 303 1573

Switchboard Fax: 0116 258 7565

Minicom: 0116 287 9852

**An Investigation into Ethical Issues of Personal Health Monitoring
Invitation Letter**

Dear Sir or Madam,

You are invited to participate in a research study on hypertension being conducted by De Montfort University. The study is looking into ethical issues of newly developed medical monitoring or "Personal Health Monitoring" devices. **Participation in the study is entirely voluntary and does NOT involve testing of any medication, medical devices or therapies.**

If you are willing to help you will be asked to participate in up to two interviews lasting approximately 30-45 minutes each at a time and place convenient for you. The included Information Sheet will explain the study and your role in further detail. Please read the included Information and Consent Sheets before deciding if you would like to participate in the study. If you would like to participate or want more information please contact the research team using the details below.

Yours faithfully,

A handwritten signature in black ink, appearing to read 'Brent Mittelstadt'.

Brent Mittelstadt

For more information or to indicate your interest in participating contact:

Brent Mittelstadt (Chief Investigator)

0750 712 1631

bmittelstadt@dmu.ac.uk

Alternatively, return this sheet to the person who gave you it (turn page over)

Version 3.0

07.03.2012

Patients - Hypertension

Trust Headquarters, Level 3, Balmoral Building, Leicester Royal Infirmary, Leicester LE1 5WW

Website: www.uhl-tr.nhs.uk

Chairman Mr Martin Hindle Chief Executive Mr Malcolm Lowe-Lauri

Please contact me regarding participation in the "An Investigation into the Ethical issues of Personal Health Monitoring" study:

Name_____

Phone_____

E-mail_____

A14.18 Invitation Letter – Disease Specialist - Diabetes



University Hospitals of Leicester



NHS Trust

Leicester General Hospital

Gwendolen Road

Leicester

LE5 4PW

Tel: 0300 303 1573

Switchboard Fax: 0116 258 7565

Minicom: 0116 287 9852

Address

DD-MM-YYYY

Dear <insert name>,

I am writing to ask whether you would be willing to meet with me to discuss how best to include patients with hypertension in a qualitative study on ethical issues of Personal Health Monitoring. Your expertise in diabetes research would make your input invaluable in the design and conduct of my study.

I am a full-time PhD student at De Montfort University. My supervisory team, Dr. Ben Fairweather, Dr. Neil McBride and Dr. Mark Shaw (a medical doctor) work in the Centre for Computing and Social Research, the focus of which is the ethical and social consequences of Information and Communication Technologies.

My research will examine the impact of Personal Health Monitoring (PHM) on relationships between patients, physicians and paying organizations, by conducting semi-structured qualitative interviews with patients having various diagnoses, including those with diabetes. I have defined Personal Health Monitoring (PHM) as any electronic device or system that monitors a health-related aspect of a person's life on a constant basis, an example of which would be a networked glucose monitor. The interviews will seek patients' perceptions of benefits and concerns regarding the use of PHM. The analysis will focus on the effect on patient/doctor/payer relationships, with a view to understanding any ethical issues that may arise.

I would greatly appreciate a brief conversation to discuss how best to recruit such patients for interviews. Ethical permission for the study has already been given by De Montfort University and I will be applying to the NHS for ethical permission to proceed once I have clearly defined my methods.

Yours faithfully

Brent Mittelstadt
PhD Student
Centre for Computing and Social Responsibility
De Montfort University
The Gateway
Leicester, LE1 9BH
bmittelstadt@dmu.ac.uk
0750 712 1631

Version 1.0

10.02.2012

Invitation Letter – Disease Specialist - Diabetes

Trust Headquarters, Level 3, Balmoral Building, Leicester Royal Infirmary, Leicester LE1 5WW

Website: www.uhl-tr.nhs.uk

Chairman Mr Martin Hindle Chief Executive Mr Malcolm Lowe-Lauri

A14.19 Invitation Letter – Disease Specialist - Hypertension



University Hospitals of Leicester



NHS Trust

Leicester General Hospital

Gwendolen Road

Leicester

LE5 4PW

Tel: 0300 303 1573

Switchboard Fax: 0116 258 7565

Minicom: 0116 287 9852

Address

DD-MM-YYYY

Dear <insert name>,

I am writing to ask whether you would be willing to meet with me to discuss how best to include patients with hypertension in a qualitative study on ethical issues of Personal Health Monitoring. Your expertise in cardiovascular research would make your input invaluable in the design and conduct of my study.

I am a full-time PhD student at De Montfort University. My supervisory team, Dr. Ben Fairweather, Dr. Neil McBride and Dr. Mark Shaw (a medical doctor) work in the Centre for Computing and Social Research, the focus of which is the ethical and social consequences of Information and Communication Technologies.

My research will examine the impact of Personal Health Monitoring (PHM) on relationships between patients, physicians and paying organizations, by conducting semi-structured qualitative interviews with patients having various diagnoses, including those with hypertension. I have defined Personal Health Monitoring (PHM) as any electronic device or system that monitors a health-related aspect of a person's life on a constant basis, an example of which would be a 24 hour blood pressure monitor. The interviews will seek patients' perceptions of benefits and concerns regarding the use of PHM. The analysis will focus on the effect on patient/doctor/payer relationships, with a view to understanding any ethical issues that may arise.

I would greatly appreciate a brief conversation to discuss how best to recruit such patients for interviews. Ethical permission for the study has already been given by De Montfort University and I will be applying to the NHS for ethical permission to proceed once I have clearly defined my methods.

Yours faithfully

Brent Mittelstadt

PhD Student

Centre for Computing and Social Responsibility

De Montfort University

The Gateway

Leicester, LE1 9BH

bmittelstadt@dmu.ac.uk

0750 712 1631

Version 1.0

21.07.2011

Invitation Letter – Disease Specialist - Hypertension

Trust Headquarters, Level 3, Balmoral Building, Leicester Royal Infirmary, Leicester LE1 5WW

Website: www.uhl-tr.nhs.uk

Chairman Mr Martin Hindle Chief Executive Mr Malcolm Lowe-Lauri



**An Investigation into Ethical Issues of Personal Health Monitoring
Invitation Letter**

Dear <insert name>,

You are hereby invited to participate in a research study on health monitoring and dementia being conducted by De Montfort University. The study is looking into ethical issues of newly developed medical monitoring or “Personal Health Monitoring” devices and their effects on relationships between doctors, patients and the NHS. **Participation in the study is entirely voluntary.**

If you are willing to help you will be asked to participate in up to two interviews lasting approximately 30-45 minutes each at a time and place convenient for you. The included Information Sheet will explain the study and your role in further detail. Please read the included Information and Consent Sheets before deciding if you would like to participate in the study. If you would like to participate or want more information please contact the research team using the details below.

Yours faithfully,

Brent Mittelstadt

For more information or to indicate your interest in participating contact:

Brent Mittelstadt (Chief Investigator)
bmittelstadt@dmu.ac.uk

0750 712 1631

Alternatively, return the detachable sheet to the person who gave it to you:

Please contact me regarding participation in the "An Investigation into the Ethical issues of Personal Health Monitoring" study:

Name _____ Phone _____

E-mail _____



University Hospitals of Leicester 
NHS Trust

Leicester General Hospital
Gwendolen Road
Leicester
LE5 4PW

Tel: 0300 303 1573
Switchboard Fax: 0116 258 7565
Minicom: 0116 287 9852

**An Investigation into Ethical Issues of Personal Health Monitoring
Invitation Letter**

Dear Sir or Madam,

You are hereby invited to participate in a research study conducted by De Montfort University on the ethical implications of health monitoring. The study is looking into ethical issues of newly developed medical monitoring or “Personal Health Monitoring” devices and their effects on relationships between patients, doctors and the NHS. **Participation in the study is entirely voluntary.**

If you are willing to help you will be asked to participate in up to two interviews lasting approximately 30-45 minutes each at a time and place convenient for you. The included Information Sheet will explain the study and your role in further detail. Please read the included Information and Consent Sheets before deciding if you would like to participate in the study. If you would like to participate or want more information please contact the research team using the details below.

Yours faithfully,

Brent Mittelstadt

For more information or to indicate your interest in participating contact:

Brent Mittelstadt (Chief Investigator)
bmittelstadt@dmu.ac.uk

0750 712 1631

Alternatively, return the detachable sheet to the person who gave it to you:

Version 3.0

07.03.2012 NHS Managers – Care Commissioners

Trust Headquarters, Level 3, Balmoral Building, Leicester Royal Infirmary, Leicester LE1 5WW
Website: www.uhl-tr.nhs.uk
Chairman Mr Martin Hindle Chief Executive Mr Malcolm Lowe-Lauri

Please contact me regarding participation in the “An Investigation into the Ethical issues of Personal Health Monitoring” study:

Name_____

Phone_____

E-mail_____

An Investigation into the Ethics of Personal Health Monitoring

Executive Summary

Research Question: How will the use of Personal Health Monitoring (PHM) affect the decisions, actions and outcomes between patients, medical personnel and medical paying organisations in the UK?

Definition of PHM: Any electronic device or system that monitors and records data about a health-related aspect of a person's life. To qualify as PHM a device must be capable of transferring data to a third party.

Study Goal: To collect empirical data supporting the identification and analysis of ethical issues of PHM prior to its widespread deployment in the UK. By definition, PHM has the potential to greatly increase the amount and detail of health data available to patients, medical personnel and paying organisations. Capturing increasingly detailed health data has potential to vastly affect the relationships between these groups in areas including but not limited to diagnosis, disease classification, resource allocation, personal responsibility for health, frequency and quality of interaction between patients and medical staff, and the classification of medical/non-medical locations. These potential effects affect users and non-users alike. In choosing whether or not to use PHM, individuals may also experience conflicting tradeoffs between privacy, comfort, safety and quality of medical care. Given these (and other as-of-yet unknown) effects of PHM, it is vital to identify and analyse the ethical impact of PHM on patient relationships prior to its deployment. The current study aims to contribute empirical data to this analysis by accessing the moral beliefs and opinions of individuals and organisations likely to use PHM in the future. Results will be published in peer-reviewed academic journals and conference proceedings.

Study Design: Qualitative unstructured interviews will be conducted with patients and NHS personnel responsible for care commissioning. Purposive sampling will be used to identify participants, allowing for analysis of existing medical relationships. An iterative design will allow for identification of theoretically interesting participants, and to determine when theoretical saturation has been reached. A total sample of 20-25 participants is predicted.

Ideal NHS Participants: PCT or GP commissioning consortia staff responsible for purchasing or commissioning health services and technologies for Leicestershire patients, or for representing the interests of patients and GPs in these transactions. Individuals meeting these criteria are predicted to have care commissioning or public health responsibilities, although the changing structure of the NHS makes prior specification of professional titles and roles impossible. Participants are hoped to be able to provide input on the current use and future prospects for PHM in Leicestershire, as well as the importance of financial considerations in commission new health services and making treatment decisions.

Interviews: Ideally, two interviews will be conducted with each participant, lasting approximately 30-45 minutes each, although one interview may be sufficient given timing restrictions imposed by the changing NHS structure. The interviews will be unstructured, meaning questions will not be formatted prior to the interview, although a list of preliminary topics of discussion will be updated prior to each interview based on the results of data analysis. The interviews will proceed from general to specific topics. The first interview will be dedicated to general questions about the professional background and responsibilities and an explanation of PHM with examples; alternatively, this information will be exchanged via e-mail if only a single interview is possible. The second interview will focus on the moral opinions and experiences of the participant as they relate to PHM. Both interviews will be in the form of a wide-ranging discussion, meaning the interviewer will contribute opinions and examples when necessary.

Sample Questions:

- How can the increasingly accurate and abundant health information gathered by PHM be used by the NHS?

- To what degree are purchasing decisions based on financial, demographic and epidemiological considerations?
- How could PHM be used in Leicestershire? Preventive care? Remote care/supplement to existing home care?
- What benefits/problems do you see with using PHM in Leicestershire?

A14.23 – Interview Guide

An Investigation into Ethical Issues of Personal Health Monitoring Interview Guide

Notes about the Guide: The following is a sample list of topics that may be covered in interviews with participants. Topics will be chosen according to the participant's background and answers during the interview. The interviews are deliberately open and semi-structured because a primary aim of the study is to uncover unknown ethical issues by allowing participants to lead the direction of the interview. The interviewer will probe answers and ask for/offer interpretations of moral concepts, but the topics covered will mostly be determined by the participant. Ideally, the section **Ethical Issues** will not be necessary, meaning the participant will actively identify ethical issues and moral concepts relevant to PHM without the interviewer raising them. Participants will not have access to this interview guide.

Beyond the introductory statement, interview topics and prompts are mostly listed as statements to avoid the interviewer asking identically worded questions to each participant. Such an approach was taken to ensure questions are phrased in a context appropriate manner, taking into account the participant's background, age, etc.

The interview guide will be iteratively revised as the study progresses based upon answers given in prior interviews. The guide below will only be used for the first interview with participants. Second interviews will be based entirely on each participant's particular background and issues raised in the first interview. The creation of an interview guide for second interviews was therefore deemed inappropriate.

Introductory Statement:

In this study we are trying to understand your opinions towards using Personal Health Monitoring technologies. We're especially interested in your opinions on moral issues and concepts the technologies may raise. Therefore, if at any time during the interview you think of a moral issue, or think a moral concept such as privacy, dignity, independence, etc is relevant, please say so.

Background:

- Icebreaker: Ask about their life, what they do/did for a living, do they like/are they good with technology?
- Current age
- Diabetes: Type 1 or 2, when did it develop? Symptoms?
- What sort of things do you do to manage your condition?
- Management of the condition: easy/difficult to cope with?
- Frequency of visits to GP, specialist, carer visits
- Any prior experience with health monitoring→Connection with management of condition?
- Technologies use for management→Health monitoring technologies?
- People that help with management of the condition.

Examples of PHM:

- Examples to be tailored to answers given in prior section. Must be relevant with person's background, disease management requirements, prior monitoring experience.
- PHM definition – Electronic device, constant monitoring, non-hospital setting, records and transmits data, may be capable of data analysis and pattern recognition, emergency alerts
- Blood pressure wrist monitor (University of Leicester) – Redefine high blood pressure
- Glucometer with built-in networking features
- Smart clothes that monitor blood glucose and other physiological signs
- *Elderly PHM (for older users):* Smart home with physiological monitoring, emergency alerts, behaviour/lifestyle feedback, medical therapy compliance, changes in health over time

- Video appointments with GP using monitoring equipment

Moral Beliefs:

- **First Question:** What's your initial reaction to (example device)?
- **Second Question:** Would you use any of the devices? Why/why not?
- **Third Question:** Does anything about the devices make you uncomfortable?
- Follow-up all answers with probes to push participant to identify and define moral concepts seen as relevant specific examples of PHM.

Ethical Issues (Prompts to be used if participant is struggling to answer prior three questions):

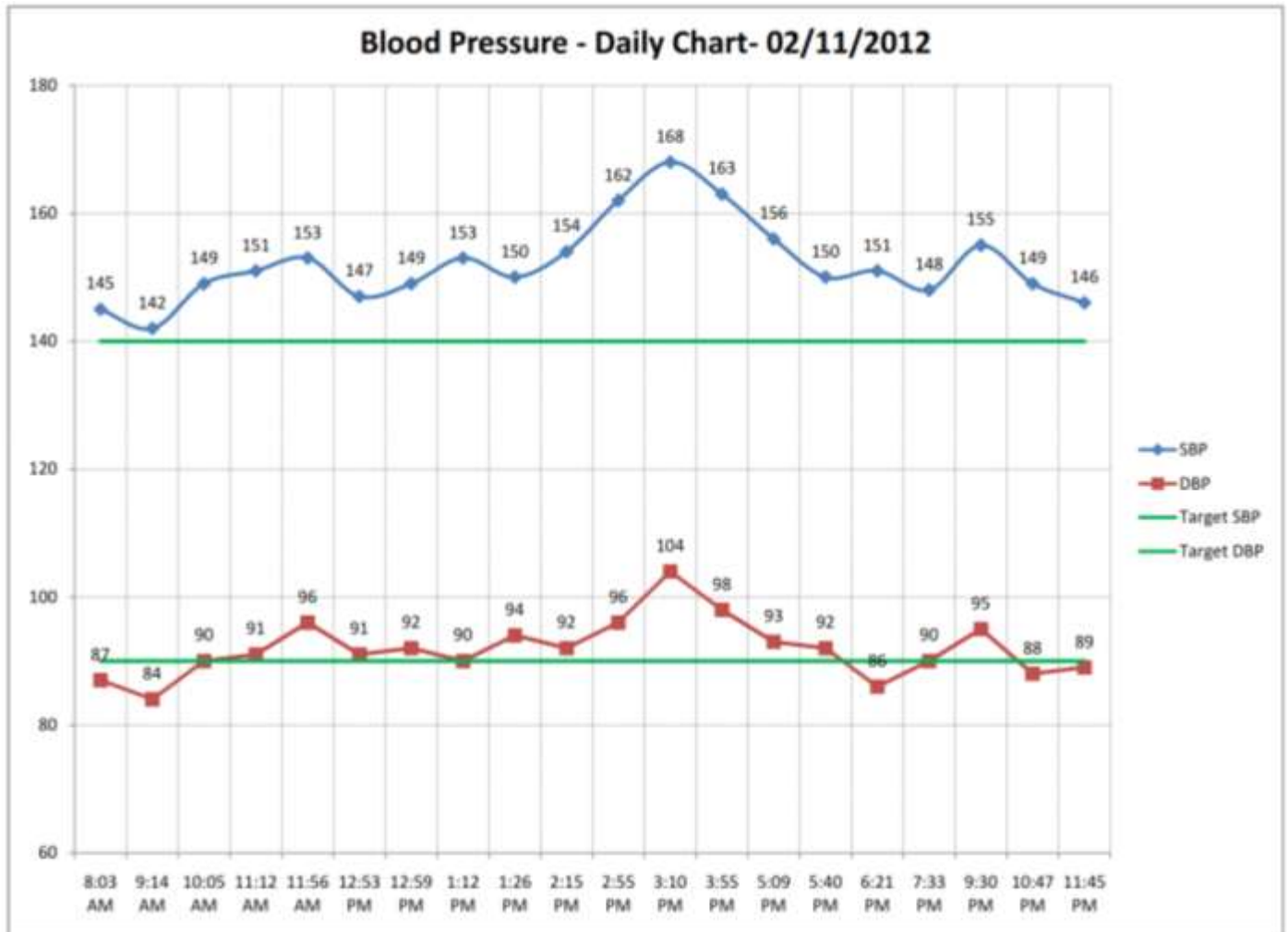
- Home installation→Obtrusiveness→Violation of personal privacy
- Invasion of the home which is a private space. What is home to them?
- Recording and transmission of data: PHM increases availability of health data.
- Identify persons they would be happy to use PHM with for management of their condition.
- Who can have access to your PHM data? (*Prompts: Family, friends, GP, nurses, specialist, NHS, researchers, private companies*).
- Would you tell your family and friends you use PHM? (*Prompts: Social isolation, stigma, power relationships*).
- How would you want your doctor to use your data? What if your data conflicts with how you feel? (*Prompts: Decontextualisation, power relationships*).
- On-site/off-site data analysis→Control over dissemination of personal data
- Would you be willing to use technology to monitor changes in your health over time?
- Aggregate data from all sources to increase the information available to you in managing your condition→"Self-management"
- Devices that make suggestions to help you be healthier or manage a condition→Behaviour recommendations/lifestyle monitoring→Issue of autonomy?
- Possibility of behaviour monitoring through data aggregation/analysis

Reflection Questions for Second Interview:

- What would your ideal PHM system do? (*Prompts: Parameters monitored, where data is sent, Mobile vs. Home installation, emergency alerts, pattern/behaviour recognition*).
- What would it not do?
- What would it look like?
- Would you want your friends and family to use PHM?
- Contact details for GP/specialist

Appendix 15: PHM Charts

A15.1 – Blood Pressure Chart with Activity Log

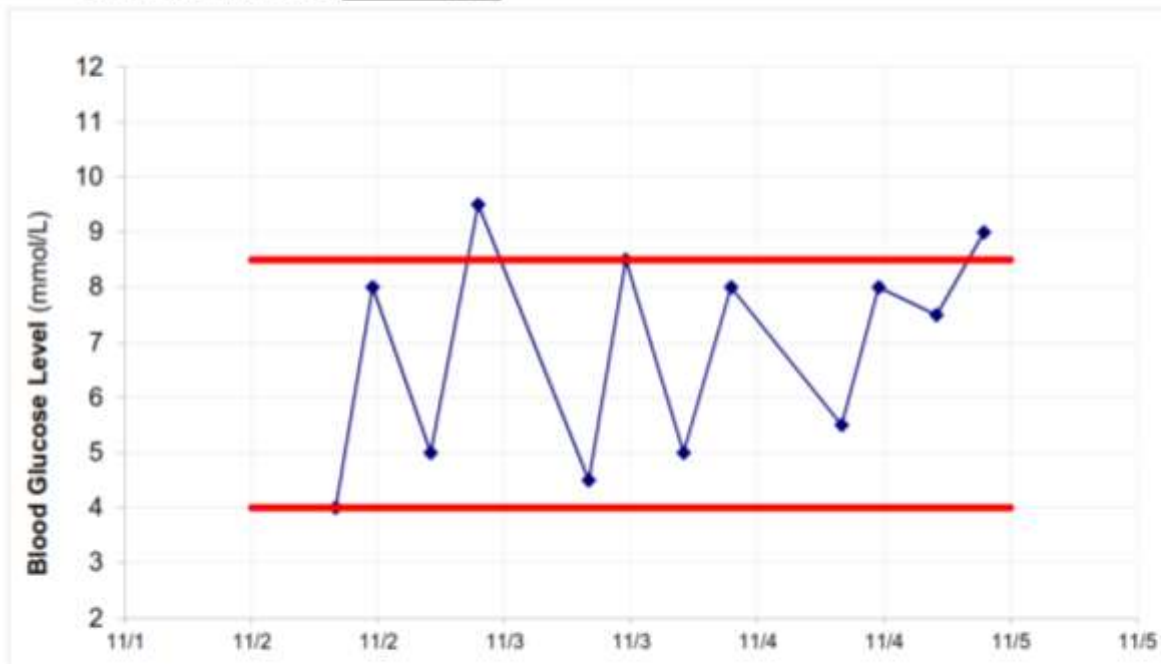


Date	Time	SBP	DBP	Activity Level	Notes
2/11/12	8:03 AM	145	87	Low	Before blood pressure medication
2/11/12	9:14 AM	142	84	Low	Unknown activity - outside house
2/11/12	10:05 AM	149	90	Low	Sitting in chair
2/11/12	11:12 AM	155	90	Medium	Cleaning
2/11/12	11:56 AM	158	96	Medium	Cleaning
2/11/12	12:53 PM	150	90	High	Short walk
2/11/12	12:59 PM	150	90	High	Short walk
2/11/12	1:12 PM	155	90	Low	Resting in living room
2/11/12	1:26 PM	150	94	Medium	Toilet
2/11/12	2:09 PM	155	90	Low	Unknown activity - outside house
2/11/12	2:50 PM	162	95	Low	Sitting on couch
2/11/12	3:12 PM	168	104	High	Sitting on couch
2/11/12	3:45 PM	163	98	Low	Watching TV
2/11/12	5:09 PM	156	93	Medium	Cooking
2/11/12	5:40 PM	150	92	Medium	In kitchen - eating
2/11/12	6:21 PM	151	86	Medium	In kitchen - using sink
2/11/12	7:33 PM	148	90	Low	Watching TV
2/11/12	9:30 PM	155	95	Low	In bed, not asleep
2/11/12	10:47 PM	149	88	Low	In bed, asleep
2/11/12	11:45 PM	144	89	Low	In bed, asleep

A15.2 – Daily Blood Glucose Chart

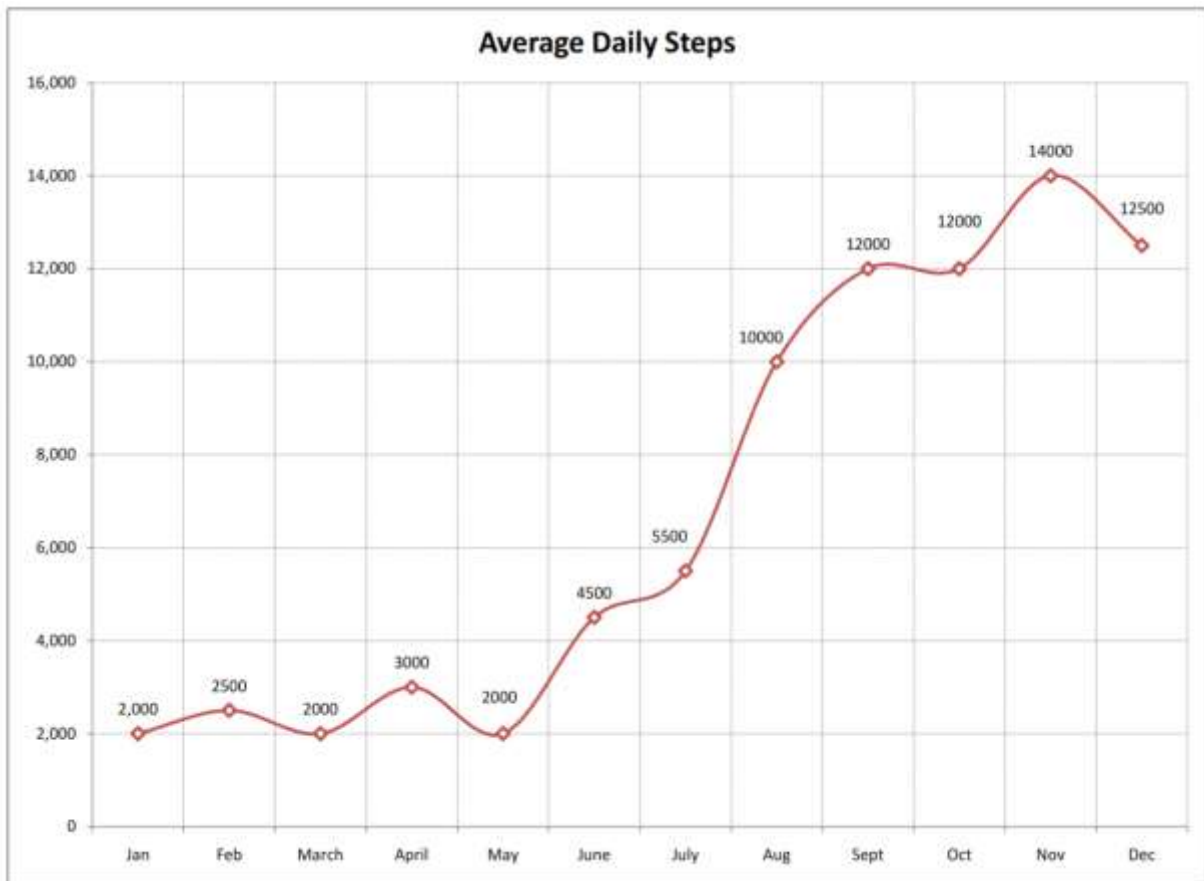
Daily Blood Glucose Chart

Upper Normal Level	8.50
Lower Normal Level	4.00



Date	Time	Level	Notes
11/2/09	8:00 AM	4	Just woke up
11/2/09	11:30 AM	8	After meal: Tea with milk, toast with jam, orange juice, fru
11/2/09	5:00 PM	5	Preparing Dinner
11/2/09	9:30 PM	9.5	After meal: Spaghetti bolognese, salad, cheesecake
11/3/09	8:00 AM	4.5	Just woke up
11/3/09	11:30 AM	8.5	After meal: Bacon, Sausages, Toast, Tea with milk, Beans
11/3/09	5:00 PM	5	Went for a walk
11/3/09	9:30 PM	8	After meal: Fish, potatoes, salad
11/4/09	8:00 AM	5.5	Just woke up
11/4/09	11:30 AM	8	After meal: Whole bran cereal, milk, coffee with milk
11/4/09	5:00 PM	7.5	Preparing Dinner
11/4/09	9:30 PM	9	After meal: Steak and eggs

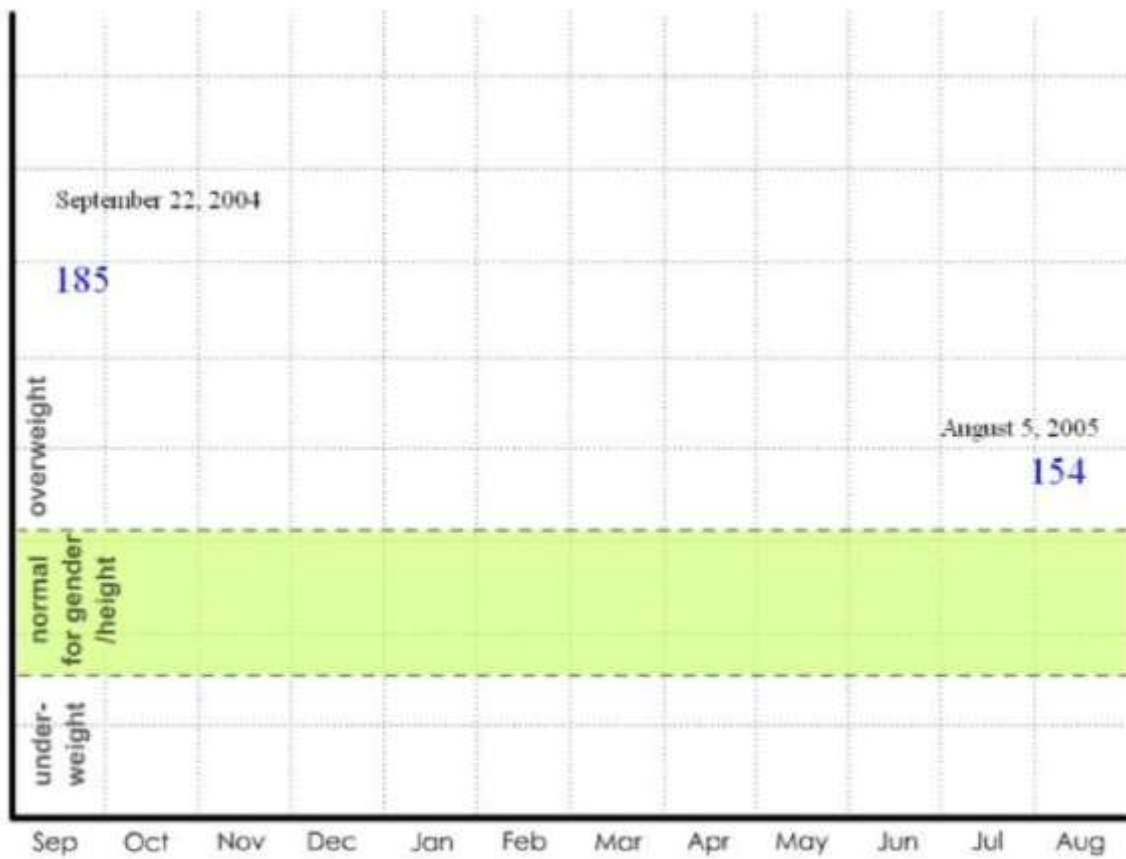
A15.3 – Pedometer Graph



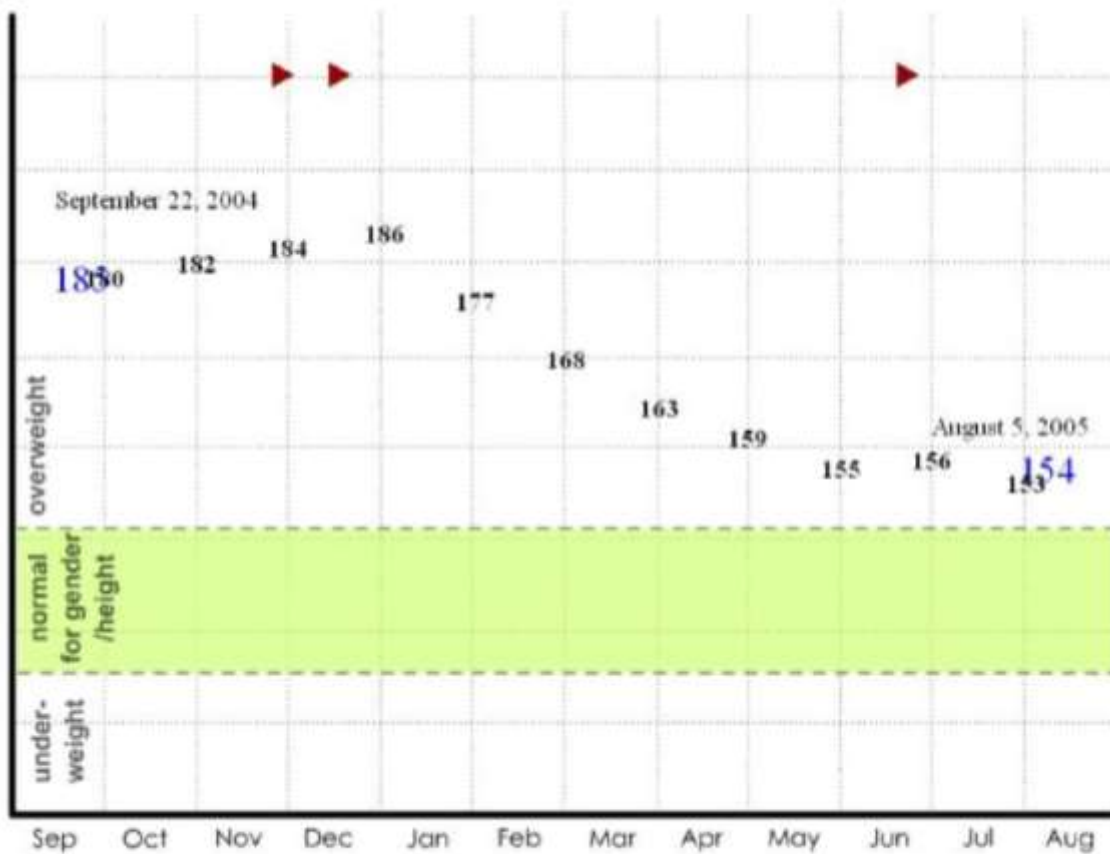
A15.4 – Weight Graph



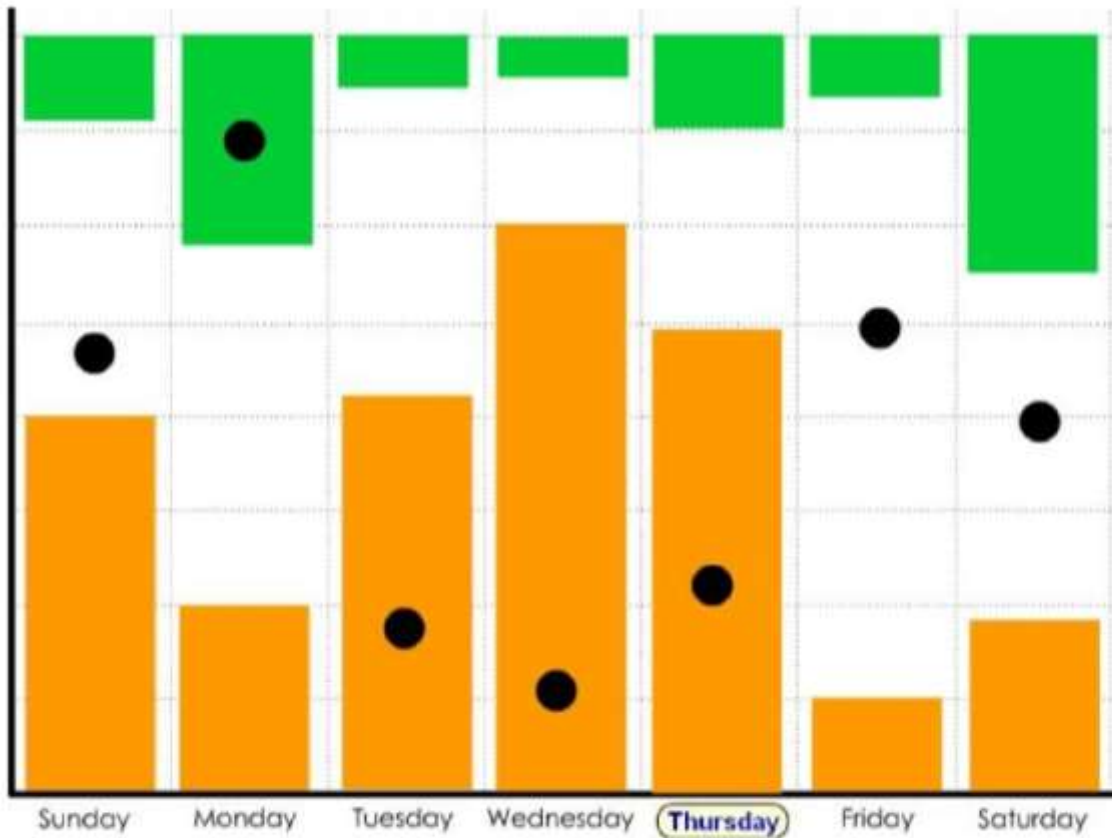
A15.5 – Interview Charts from Beaudin et al., 2006



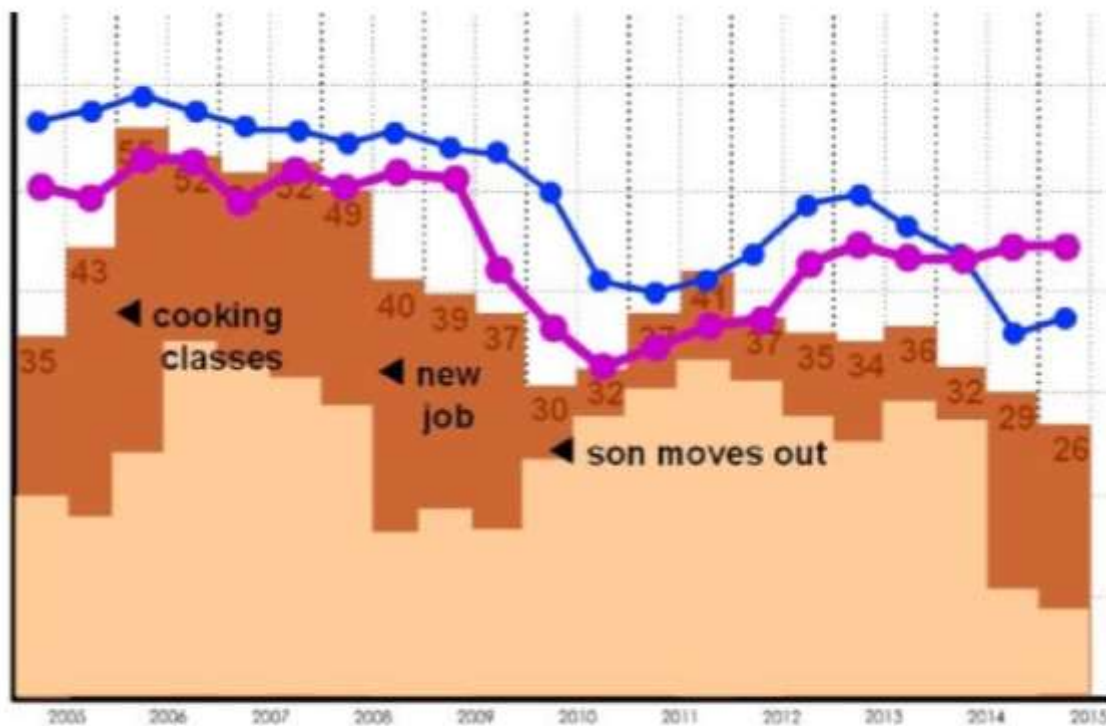
Weight displays: (a) traditional clinical weight data



(b) home monitoring weight data



Time scale displays on (a) time spent watching TV (orange: TV watching; green: time spent outside; black dots: mood rating)



and (b) variables that may be sensitive to major health changes

Appendix 16: Sample Interview Transcripts

DP1 - First Interview

00:00 **Interviewer:** So umm to start off, just a couple things, I guess, about the point of the, of the interview. It's to find out what your opinions are on moral issues and moral concepts, ethical problems we think may exist in association with personal health monitoring. So, I'll explain a bit more about what the technology actually is, and what we think some of the issues may be a little later in the interview. But, I just want to make it clear that anything that we're talking about, if you think that there is some moral issue there, or there is some concept like privacy or dignity or independence, or something like that that you feel is relevant, the by all means, you know, say that. Because that-, we're trying to capture. We're trying to understand your opinions towards the moral issues and we're also trying to understand how you think using one of these technologies would effect your relationship with other people.

00:55 **DP1:** OK.

00:55 **Interviewer:** Umm so the first thing, I just want to hear a bit more about yourself, about your background, and about your condition.

01:04 **DP1:** Right. But, so my condition, really, I was diagnosed not quite two years ago, really. Umm I'm controlling it with diet. Umm I have had cancer and chemotherapy, and I've put a lot of weight on. So, I think that was probably the trigger for the diabetes, because there is no diabetes in my family at all. So, whether that, you know, the weight, quick coming on with the weight, probably triggered [??]. I've lost three and a half stones since I was diagnosed. And it's actually brought my sugar levels down now to five point nine BH, B, whatever it is, 1C, reading.

01:44 **Interviewer:** Mmm.

01:45 **DP1:** So, from nine point, something, it's come down to five point nine, just from losing weight and diet. So, I'm not on any medications, so a lot of the machine, the testing things, wouldn't be applicable, probably, to me anyway. But, I still have umm an idea of what it's like for other people, because I do know other people who have diabetes. So, you know, so. That's, basically, my medical thing with the diabetes. So, do you need to know anything more about err . . . I don't know, other things other than the medical condition?

02:23 **Interviewer:** I'm happy to hear about anything you want to tell me, to be honest.

02:25 **DP1:** (coughs) (laughter)

02:28 **Interviewer:** I mean, I would love to know a little more about you.

02:29 **DP1:** (laughter) I'm 62. I've been retired for nearly five years. I've got three sons, five grandchildren. Umm I've lived a fairly healthy life really, until I got cancer. That was umm and then, that changed a lot of things, really. Yeah, but I'm a happy person and content with my lots, and yeah, yeah.

02:51 **Interviewer:** Good. Is it umm, what type of diabetes is it?

02:55 **DP1:** Two.

02:56 **Interviewer:** Type two, OK. And, do you mind me uhh, do you mind me asking about Paul at all? I mean, you don't have to tell me about-

03:02 **DP1:** You-, you-, no, I don't mind you asking about Paul.

03:04 **Interviewer:** OK.

03:04 **DP1:** He'd be quite happy for me to tell you, anyway.

03:06 **Interviewer:** OK. What uhh, what type does he have?

03:08 **DP1:** He is-, he's been uhh diagnosed as pre diabetic.

03:12 **Interviewer:** OK.

03:13 **DP1:** Because he took part in a uhh study program umm which he was recommended to go on with the-, from the doctors. It's something from the surgeries. And they picked up that he was pre diabetic. He was then-, there were one group who were given the opportunity to have some umm information and such, like, to help deal with the condition, who were in similar position. And another group, where there were going to do nothing with. And Paul, unfortunately, came into the nothing group. But, from his point of view, he was quite fortunate because I was diagnosed-, I was diagnosed with diabetes at the same time. So, but not on that study. This was quite independent. And, I was on the Thomas Desmond course, which I expect you know about.

04:03 **Interviewer:** Yes.

04:03 **DP1:** Yeah. So, I could take somebody with me if I wanted to, so he came with me. So, he got all the information that the other study group were going to have, so he is also has been following the same machine that I have been following, and its now brought his umm levels down really low, to well into the umm acceptable. And it's not a problem for-, as such. But, of course, with these things you've got to maintain it, otherwise you just go straight back.

04:31 **Interviewer:** Right.

04:32 **DP1:** So-, so really, from his point of view, he's umm, he's sort of acting as if he was a diabetic, because he knows that's going to keep him healthy. And so, yeah, so that's what helped him. And uhh, he-, his-, one of his things that came up, you see, he had a heart attack, so that may have-, but it runs in his family, heart attacks and things. And his father was diabetic. And, so there may be a history there of-, of a condition, really.

05:03 **Interviewer:** OK.

05:05 **DP1:** Yeah.

05:06 **Interviewer:** So, Desmond gave you-, what was it exactly, it was lifestyle guidance-

05:10 **DP1:** Yeah.

05:11 **Interviewer:** -sort of.

05:11 **DP1:** Yeah. Well, they don't give you a specific diet. But, they-, you-, it's very intense day, and it becomes very obvious, you cut out sugar, you cut out fat, you take more exercise. Umm, you know, just simple, really, sensible things, which we all know we should do but don't. Because you think, I'm OK.

05:34 **Interviewer:** Right.

05:35 **DP1:** Like everybody does. But, they were-, they really droned it home and you're-, you knew exactly what you've got to do when you came away. So, that's what we do, we actually look at everything. Any labels on anything, we look at. And, we keep our sugar levels really low, and that seems to be working on their own. We've both lost weight, so-

05:57 **Interviewer:** So, you monitor your sugar levels at home?

05:59 **DP1:** No.

05:59 **Interviewer:** OK.

06:00 **DP1:** Because, I think even if you have umm the litmus papers with urine, it's already-, it has to be up to about 10, doesn't it, the level, before it shows. Well, because we're both below, there's no point in doing that.

06:14 **Interviewer:** Right.

06:15 **DP1:** Umm, and the blood umm my doctor, you know, testing of the blood isn't really appropriate at the levels that we're at.

06:23 **Interviewer:** Right.

06:24 **DP1:** Umm but-, and I-, I have-, when I realized that I was being diagnosed as a diabetic, before I was actually told, 'cause you know, you can fairly sense that that's where it's going. People I had spoken to said to me, 'Well, you can manage it with diet.' But then, there are other people that say it's impossible. So, when I spoke to my doctor I said that I wanted to try the diet, going down the diet route first. Because once you go on medication, you're more or less stopping it, aren't you? And you've got nowhere to go at a later date.

06:59 **Interviewer:** Mm-hmm.

06:59 **DP1:** So, my doctor's been quite supportive in that. So, I mean, I don't go as much now, but initially he saw me quite a lot. Lots of checks, and now I'm having umm, I think it-, I'm going to have an annual check now. Because I've got it under control. So, as long as I do what I'm supposed to do, I will presume I'm going to be reasonably all right for a while.

07:24 **Interviewer:** Mm-hmm.

07:24 **DP1:** Yeah. Yeah.

07:26 **Interviewer:** So, does the-, besides the uhh information that you tell him, say, during an annual check or the more frequent checks that you had, is that really all the information that he's uhh basing his decisions on? Or, do you tell him anything about, like, your home life or-

07:42 **DP1:** Uhh, not really, I think it-, because he-, they-, they do blood tests and weight, umm, measure my waist size. Do the testing of the feet, I've seen a podiatrist and things like that. So, I think-, now that-, because he knows that I'm clued up on it, really. And know what I've got to do, and that I've been doing it. Because of the results of all the tests that are now coming back in, I think he's happy to leave me to do it. Because he probably knows me well enough to know that I will continue doing it. Maybe some-, I do know other people who don't bother. And they think oh, you know, they'll just carry on doing what they want to do.

08:22 **Interviewer:** Right.

08:22 **DP1:** But, I'm fully aware that if I do that, I'm going to go back. And I know the consequences of what happens when diabetes gets out of control, 'cause I've seen it. And this is another thing, too, they've been driving home on the Desmond course, is these things happen to you. So, but my doctor's probably content with that, 'cause he knows the kind of person I am. I think that makes a difference, if you know your doctor.

08:47 **Interviewer:** Mm-hmm.

08:48 **DP1:** So, yeah. Umm, but if I was concerned about anything, I would go there straight away. You know, I won't-, won't be sitting about thinking, 'Is it this, or is it that.' I'd just go, you know.

09:01 **Interviewer:** So, the main-, the main thing that you do then, just to sort of summarize what you said, uhh, it sounds like the main thing that you do to manage and monitor your diabetes is the, uhh, diet and exercise at home.

09:15 **DP1:** Yes.

09:15 **Interviewer:** And not so much anything with blood monitoring or glucose-

09:19 **DP1:** No.

09:19 **Interviewer:** -or anything like that.

09:20 **DP1:** That's just gone on continually, no.

09:23 **Interviewer:** Right.

09:23 **DP1:** Yeah.

09:25 **Interviewer:** Right. So then, it sounds like your GP is the main person that you see-

09:27 **DP1:** Yes.

09:28 **Interviewer:** -as far as management.

09:29 **DP1:** Yeah. Yeah. Well, uhh, yes. I see him and I see the nurse, but that's all combined, if you know what I mean. Umm, it's because of the GP, the last time I went and had all of the tests done and the nurse, umm, in fact she's my friend, I'm not going to (laughter) lie, so, yeah. She-, she went through everything with me and said it was OK, so. But I know when I have been to see my doctor

about something else, he'll check it all-, he'll just bring it all up on the screen and just check for this-, all going OK. Yeah. So-

10:05 **Interviewer:** Right. OK. Umm . . . I'm just trying to think of which technologies might be most relevant to-. Well, let me just-, I'll explain the technologies now, that we're looking at. Personal health monitoring, again, refers to a whole different-, or a whole wide group of technologies. The main thing that they have in common-

10:31 **DP1:** (cough)

10:31 **Interviewer:** -is that it's a device that you can use at home or when you're on the go. It in some way monitors some aspect of your health on a constant, or a semi-constant basis. And it is capable of transferring the data it collects to a third party of some sort.

10:49 **DP1:** OK.

10:50.02 **Interviewer:** So, it could be a GP, a nurse, call center or emergency alert center, private company even, depending on who is actually controlling the device, who designed it and who is using it. Uhh, but they-, so those are the main things that they have in common. The ones that are probably-, some examples of ones that are probably most relevant to diabetes, umm . . . first would be a, ahh, glucometer, or blood monitor that you could use at home that would actually transmit the whatever data it collects to your GP. And you-, depending on the design, you could have control over when it transmits, or you could just do it automatically. Umm, another example would be, uhh, they're actually developing what are called smart clothes. And smart clothes actually will have, umm, sort of nano or micro processors basically woven into the clothing.

11:44 **DP1:** OK.

11:45 **Interviewer:** That are capable of measuring some physiological sign. So, it could be heart rate, it could be breathing, but it could also be, again, blood sugar and glucose levels. So, you could literally, literally be wearing a shirt that's monitoring you on a constant basis. Monitoring your health. And, again, it would have that ability to collect that data to aggregate-, or to collect it in one place and send it off to someone else.

12:09 **DP1:** OK.

12:10 **Interviewer:** Umm, I suppose that's the most science fiction sort of sounding one (laughter)

12:15 **DP1:** (laughter)

12:15 **Interviewer:** Probably, uhh, the most likely one that's going to be used in, in the country, are what are called smart home technologies. And that, again, is massive range of different technologies that are being developed. But, basically, the-, the-, what they do is it's a technology that's embedded in your home. So, it could be sensors are put into your home, or even built into your home, ahh, when the home is being originally constructed. And these sensors can detect all sorts of different things about your lifestyle and your health. And so, some examples, and these may not be diabetes specific, but certainly they're relevant to, umm, uhh, I should say, most smart home technologies are designed for older people. Or people that are aging or need some sort of help at home. So, yeah, the-, the type of things that-, that they could monitor would be, say if a person has a fall-

13:10 **DP1:** Oh, that's interesting.

13:12 **Interviewer:** If a person is sitting in a chair, umm, if they've fallen asleep in the chair, could measure body temperature, again, physiological signs, heart rate, umm. Could measure, err, when someone leaves their house, when someone enters a certain room in their house. Umm, it could-, what else could it measure . . . They can measure medication compliance, or compliance with a recommended treatment by a doctor. Umm, so if the doctor, say, recommends that you get up and exercise for 30 minutes every day. Presumably the sensors could actually detect if you were doing that.

13:49 **DP1:** Yeah Oh, I could see people objecting to that.

13:56 **Interviewer:** Yeah.

13:57 **DP1:** 'Cause they would-, they would think they are being watched all the time. Yeah, that's, umm, that's really weird. I would have to give a great deal of thought about that if that was-, do you know what I mean?

14:08 **Interviewer:** Yeah. Yeah.

14:08 **DP1:** Suggested putting that in my home, I think that, well-, yeah.

14:13 **Interviewer:** I should be clear, I'm not going to put anything in your house. (laughter)

14:14 **DP1:** (laughter) I know you're not, but I'm just thinking, it-, you said-, I-, I'll go off on one now, 'cause I'll start thinking, 'Oh, crikey!' I know I can see a lot of people who would really object to that.

14:25 **Interviewer:** Yeah.

14:26 **DP1:** Yeah. Yeah.

14:26 **Interviewer:** Yeah, I sort of from the-, the more acceptable ones-

14:31 **DP1:** Yeah, the more extreme, 'cause I'm being monitored, like, you can have a blood pressure monitor on, can't you, uhh, for a day, for 24 hours or something. I was thinking it was on those sort of lines, not like fitting your house out with a-

14:45 **Interviewer:** It-, it is those lines, too, though. Another one that I didn't mention, uhh, was a blood pressure risk monitor.

14:51 **DP1:** Yeah.

14:51 **Interviewer:** That-, just like a watch that you would wear-

14:53 **DP1:** Yes.

14:53 **Interviewer:** That you would wear it on a constant basis.

14:54 **DP1:** Yeah. Yeah. So, it just gives somebody somewhere a pattern of things that are happening then. Is that what the information is about?

15:03 **Interviewer:** It could be, yeah.

15:04 **DP1:** Yeah. So, then if-, if-, I suppose if were-, if your diabetes was so bad and you had heart problems and things like that, somebody could be informed about it then, if you were a person living on your own. Would that come up quickly? Would somebody be able to detect that, and find-. Sorry, I'm just-

15:22 **Interviewer:** You mean, to detect changes?

15:24 **DP1:** Yeah.

15:26 **Interviewer:** Emergencies:

15:26 **DP1:** Yeah. So, would that-, is that the kind of information it's collecting?

15:30 **Interviewer:** It could, yeah. It-, it's collecting raw data about your health.

15:34 **DP1:** OK.

15:34 **Interviewer:** Umm, so whatever-, whatever sign or whatever physiological thing it's meant to monitor, it's just collecting a bunch of data about that. And then, what could happen is either the device itself could do some sort of processing of the data and say, 'Oh, here's a problem,' and alert someone. Or it could just be the raw data sent off to a center where some computers, or even some people, actually analyze the data and come up with a-, with the patterns and the, uhh, the alerts and that sort of thing.

16:02 **DP1:** Yeah, so that's what you're heading towards then, with all this information? Trying to-, trying to find patterns of certain things that happen, or is it people's behavior that helps to contribute to their condition, or-

16:17 **Interviewer:** It- it's all those things. It can be looking at behavior. It can be looking at patterns in the-, in their health, and patterns in the disease. It can look at how they're managing a disease. Umm, it can-, it can alert someone if there's an emergency situation, and get someone out to the house immediately. That's a big part of it. Umm . . . essentially they're meant to help you manage your health in some way.

16:47 **DP1:** Well, I was wondering what the actual point of it all was, really.

16:50 **Interviewer:** Basically safety and helping you manage your health.

16:53 **DP1:** But, do you think people would use it for that? Because people, I mean, I know people who've got the machines now that test the blood and do the strips. And they monitor their sugar levels are high but they don't actually do anything to rectify it, I mean, I went out with a friend the other day who's diabetic and she used her, uh, blood testing one and it was 16 point something. Now I had a diet Cola to drink. She had lime and lemonade.

17:35 **Interviewer:** Mmm.

17:35 **DP1:** And I thought, why are you doing that when you've got...you sugar's at that level? So, do you think people would actually put the information to use with these?

17:50 **Interviewer:** I don't, I don't know.

17:53 **DP1:** (Laughter)

17:53 **Interviewer:** I was hoping you might be able to tell me.

17:55 **DP1:** Well this is it. This is why I was saying and I know people would do it with strips and they...but they're already high when...if it's showing like 2 points over. They're already too high anyway.

18:05 **Interviewer:** Mmm.

18:05 **DP1:** And they don't seem to...I mean, I know, and they, they eat cakes and biscuits. At the diabetic meeting at Christmas, for instance, we had a little get-together and everybody took some food. I took (incomprehensible) food but the amount of cakes and biscuits and chocolates that were there, were unbelievable. And they're not...I can't understand why people would even bother to eat them. So that's why I'm wondering whether this technology will actually be of any use. Whether, whether it's just using a lot of money that doesn't need to be used?

18:42 **Interviewer:** Well certainly, some of it is going to be down to the emergency alert idea and just assisting people in their own home. Especially...you have to think about elderly people in their own home that may need assistance...

18:54 **DP1:** (coughing) Yeah.

18:54 **Interviewer:** (incomprehensible) ...certainly...I mean, that's one aspect of it but as far as...it sound's like what you're talking about is, will people actually use the information to make choices to improve their health?

19:03 **DP1:** Mmm. I am. So, I'm wondering whether it's (coughing), whether it's worth spending that much money on it. Do you know what I mean?

19: 09 **Interviewer:** Yeah.

19:11 **DP1:** Because I know so many people who don't know bother. But I do know people like myself who do. It's not everybody like that. I know a lot of people who do make an effort but.

19:24 **Interviewer:** What about yourself, could you pos-, could you see yourself using any other technology I was talking about to help you manage your health?

19:32 **DP1:** I mean, at the moment, I don't know that I actually need to. If I was...my sugar levels weren't stable or improving, then maybe I would because I would want to control it.

19:45 **Interviewer:** Mmm.

19:47 **DP1:** Um, and so, yeah, maybe I would. It would depend what it was really.

19:50 **Interviewer:** OK.

19:51 **DP1:** But I mean, it would be interesting...I mean my blood pressure's come down now but that was quite high at one time. And ...so there would've been a point then when you could...it would've been good to have had a better, um, idea of how my blood pressure was, was at particular

times but...and then I, I don't know quite...I had to have discuss it with my doctor what was the best way to deal with it. I mean, obviously, I've dealt with it by losing weight and I've taken more exercise. I think that's helped a lot.

20:25 **Interviewer:** Mmm.

20:25 **DP1:** But, um, I don't that...I don't know what you would use to monitor me at the moment as I've not just dipped after the last six was a boundary and hopefully with me continuing the way I am, I gonna go down a little bit more.

20:38 **Interviewer:** Well, let's say that we have won the, um, monitor just your general physiological science, signs and then also you could input data into it. In say the exercise you're doing and the food that you're eating. Cause it seems like those are the two main things that you're, that you're managing...

20:58 **DP1:** Yes.

20:58 **Interviewer:** ...at this point.

20:58 **DP1:** Yeah. Yes.

20:59 **Interviewer:** So you could put that information in there. You could also take the data that's collected about your internal, your internal health. And sort of spit out some recommendations and say, well, you know, here's, here's where you're at. Um, if you continue on this track, then you know, you're on, you're on, ur, in line to say lose, ur, another stone (?) or something like that.

21:20 **DP1:** Yeah.

21:21 **Interviewer:** Um, but maybe, here's some...based on what you do during your day, based on your behavior during the day, here's some other things you could change to, you know, improving.

21:30 **DP1:** Yeah. Right. Yeah. Yeah. Although I probably would, would be quite interested in that then because obviously I don't...I want to get as well as I can be, I think, really. And one of the interesting things is about, um...also I know diabetes causes heart attacks and strokes. That's sort of in my family, heart attacks and strokes. So, there's that possibility like monitoring that kind of thing would probably be helpful as well. Cause you'd know if...how fit you were. Cause at one time, Paul and I were extremely fit. We did a lot of running and...well, I did triathlons.

22:11 **Interviewer:** Mmm.

22:11 **DP1:** Um, but then I had quite a nasty accident in, in a race and it just put an end to all of that because I got broken up pretty badly. (laughter)

22:22 **Interviewer:** Mmm.

22:23 **DP1:** Um, yeah, so, I know I'm not as fit now as I was then. But I know I'm also a lot fitter than a lot of people my age because they don't do anything at all.

22:33 **Interviewer:** Mmm.

22:33 **DP1:** Although I only walk now. Um, so, you know, it would be quite interesting to have some levels of your general condition, I suppose, and all the general health things really.

22:47 **Interviewer:** Mmm. Mmm.

22:51 **DP1:** So, yeah, I wouldn't object to that, that sort of thing. And I don't see that problems anybody else. But I was, um, anybody else knowing, because it...like I went out Saturday night for a meal and all the people we were with wanted dessert not (incomprehensible).

23:07 **Interviewer:** Mmm.

23:07 **DP1:** But the restaurant did cheese and biscuits and they were really good. When I said I was diabetic, they made sure I only had celery(?) biscuits because they did have sweet biscuits as well. They did try quite hard to make sure I didn't get any sugar. So, I'm not bothered about telling people about that I've got diabetes.

23:24 **Interviewer:** Mmm. Mmm.

23:25 **DP1:** But I think some people might, might be. Cause people have different ideas (incomprehensible) their health and what people know.

23:39 **Interviewer:** Yeah.

23:37 **DP1:** So.

23:38 **Interviewer:** Well, that raises an interesting point. Let's, let's say we're doing, um, the monitoring we just talked about. So, let's call it lifestyle monitoring.

23:47 **DP1:** Mmm.

23:47 **Interviewer:** It's helping you to improve your lifestyle to manage your disease. Now, there are couple different ways that we could do that. One is that you could have a device that you carry around or wear on you most of the time. Um, another could be that we put sensors all around the house that, that do the same thing.

24:06 **DP1:** Mmm.

24:06 **Interviewer:** Um, what are you feelings on those two, two options?

24:10 **DP1:** I would prefer to wear something because then I would feel it wasn't as intrusive because if it decided I didn't want to, I could take it off or something like that. Where as if you've got your sensors in your house, unless you've got a switch and you want to switch it off. Um, I feel that is a little bit intrusive. I would begin to...yeah, but I don't know why the difference is between wearing something and having it in the house that's...I don't know why I feel that because it's only doing the same thing, isn't it?

24:42 **Interviewer:** Yeah. It's, it's monitoring the same thing.

24:45 **DP1:** Yeah, but for some reason to think that it's in your house is a bit unsettling, I think. Just because we all have this thing about big brother, don't we? (laughter)

24:59 **Interviewer:** (laughter)

25:00 **DP1:** You know, whereas if it's on...I feel as if it's not in my control if it was in the house whereas if it was on me, it's in my control. That's...

25:07 **Interviewer:** Even if there was an on and off switch in the house?

25:11 **DP1:** Yeah. I think...I'm...yeah. So, so how would it distinguish between myself and other people came into the house?

25:17 **Interviewer:** Well, there's one problem. It may not be able to but let's say that, um, for example, you could have, ur, just a little card in your pocket that had what's called a, ur, RFID chip...

25:32 **DP1:** Oh yeah.

25:33 **Interviewer:** ...a radio frequency identifier.

25:34 **DP1:** Yeah.

25:34 **Interviewer:** So then it will know based on that little card you carry around that it's you.

25:37 **DP1:** Right.

25:38 **Interviewer:** And if it can't find you, I won't monitor anybody but...

25:42 **DP1:** Yeah.

25:42 **Interviewer:** ...so it monitors just you. Let's, let's say that, that...I mean it doesn't sound like you really want it in your house anyway but let's say that it was in your house...

25:51 **DP1:** Mmm.

25:52 **Interviewer:** ...and would you, would you use it at all if you couldn't have that, that, ur, separation between you and other people in the house?

25:59 **DP1:** If I couldn't have it between other people, no. Because then I intruding unto other people's personal, um, um, space. You're invading other people's privacy, aren't you? If it takes other people it would have to be solely for myself.

26:14 **Interviewer:** OK.

26:14 **DP1:** I wouldn't want to because I don't think that would be right. I can't give permission for monitoring of other people.

26:22 **Interviewer:** Mmm. Mmm.

26:22 **DP1:** So, I think that would, you know, I wouldn't, I wouldn't agree to that. The other thing about the housing is, it would never occurred to me that it would be like that. So, that's something I've not given a lot of thought to and my initial reaction is, I find that just a little bit, I don't know, intrusive or scary but it's in between. I'm not sure about it.

26:47 **Interviewer:** Mmm. Mmm.

26:47 **DP1:** And I don't know why it should, why I should feel different about it cause I've not had time to think about it. I do feel differently about it for me actually wearing something. Because once...I think because...yeah, now I've just...because if I'm wearing it, it's personal to me and I'm not intruding on anybody else. Um, I think maybe.

27:14 **Interviewer:** But then if...

27:14 **DP1:** Because it's OK for me to give this... to give permission for myself.

27:20 **Interviewer:** Right.

27:20 **DP1:** But even if it's only monitoring me, I don't that I would...

27:23 **Interviewer:** You'd still have a problem?

27:25 **DP1:** Yeah. I think I'd be worried about other people. I don't know why I think that because this is the first I've heard of it and I haven't had time to think it through completely.

27:32 **Interviewer:** Let me, let me make a different argument to see, just to see what you think about this. Um, I would say, hypothetically, that it's better to just have it in the house than to have it with you at all times because when you're wearing it, it means that it's monitoring you both in your house and when you're out in the world. Whereas, if it's imbedded in the house, you can actually leave the house and get away from it if you need to. If you're feeling uncomfortable with it.

28:00 **DP1:** Yeah.

28:00 **Interviewer:** What'd you think about that idea?

28:01 **DP1:** But then how does it monitor my exercise?

28:04 **Interviewer:** Um, well, (incomprehensible) may not be able to.

28:12 **DP1:** Because my exercise is outside.

28:14 **Interviewer:** Yeah. Yeah. Um, let's say, you could tell it what exercise you did. So, you walked this distance for this mile and time.

28:23 **DP1:** So, I've got to be honest then. (laughter)

28:24 **Interviewer:** (laughter) This is a problem.

28:25 **DP1:** Yeah. I can see a little problem.

28:28 **Interviewer:** (laughter)

28:28 **DP1:** Yeah. I would be honest but I could see (incomprehensible) because even not being honest, my sister-in-law said to me one day, she walks hard in 10 miles. So, we went off on a walk. We only did four miles and before we'd done two miles, she was exhausted.

28:46 **Interviewer:** Mmm.

28:46 **DP1:** And so, she had totally miscalculated what she was walking.

28:52 **Interviewer:** Mmm.

28:52 **DP1:** The distance she was walking. So, I see a problem with that.

28:55 **Interviewer:** Mmm.

28:55 **DP1:** And having run as well, knowing distance, I know how people over state what they've been running...

29:04 **Interviewer:** Right.

29:05 **DP1:** Because they just don't really know the distances.

29:09 **Interviewer:** Ur, out of curiosity, do you have a mobile phone?

29:12 **DP1:** No.

29:12 **Interviewer:** You don't? OK. Um, what I was going to say is when you're out of the house, maybe you could link up with your mobile phone which a lot of them will have GPS in them now. So you could actually tell where you've been and...

29:22 **DP1:** (incomprehensible) so that will...

29:23 **Interviewer:** ...measure your exercise that way.

29:24 **DP1:** ...that would, yeah. Well, most people have mobile phones but I'm a bit (incomprehensible) (laughter).

29:31 **Interviewer:** (laughter)

29:32 **DP1:** I just don't have time for a mobile phone. I don't want people ringing me up when I'm on my walk. So (incomprehensible). Yeah. Yeah. No, so, I don't...yeah, I'm still like this about in the house. I don't know.

29:45 **Interviewer:** I'd be interested to find out what exactly bothers you about it. But I realize you need time to think about it.

29:53 **DP1:** No. I don't know. I don't, I don't know why I feel that way. It seems odd. It seems odd to me to think I feel that way.

29:59 **Interviewer:** Mmm.

29:59 **DP1:** Because it's doing exactly the same job. So, I don't know why I feel that way at the moment. I've not thought it through.

30:08 **Interviewer:** Well, I tell you what we could do. That might be a good place to end. Um, I think I mentioned in the paper, that, that preferably I'd like to do two interviews and...

30:16 **DP1:** Yes.

30:16 **Interviewer:** ...do another one in about a month to a month and a half's time.

30:19 **DP1:** Yeah.

30:20 **Interviewer:** But what I'm thinking is that if we do that, then that gives you some time to think about why you might be uncomfortable with it in the house.

30:25 **DP1:** Yeah.

30:26 **Interviewer:** And we could, we could return to that next time.

30:27 **DP1:** OK.

30:27 **Interviewer:** That sounds good?

30:29 **DP1:** Yeah, that sounds fine. Yeah. Cause I do need to think about that because even saying it seems strange to me. But for some reason there's that little feeling there about it. I don't know why.

30:40 **Interviewer:** OK. The other...the only other thing I would ask you to consider in between the two would be, if you could have one of these devices for free, um, what would your ideal device do? And what would it not do?

30:54 **DP1:** I think it would monitor, uh, I'd like it to monitor my general health because, um, that's really important but it...I don't know. Because I'm quite, I'm quite disciplined with the exercise and the dieting, I think. Well...it's not so much a diet. It's just the way I've changed everything I eat. I don't...I have reduced amount I eat but I'm not on a strict...I don't go to Weight Watchers or anything like that. But I am quite disciplined about it so I don't know that...but there again, perhaps if it was monitored sometimes you would think, oh, I'm doing that and I should be really.

31:39 **Interviewer:** Mmm.

31:39 **DP1:** You know. Because you can suddenly start doing something and not really realize. So, I don't know. I think my general health is my main concern really.

31:50 **Interviewer:** Right.

31:50 **DP1:** And keeping the sugar levels low. Um, it would worry me...like I'm having a year now before I have any more tests. I want to make that my year... I don't do anything in that year to push those levels up, you know. So, I've got to maintain it because somebody from the group that we're going to she suddenly announced, oh, I'm on a diet because my review is due. But she hasn't bothered about it eight months before.

32:15 **Interviewer:** Mmm.

32:15 **DP1:** ...Um, yeah. So, I don't know that I really need to (incomprehensible) that way but maybe that would be a thing, you know. Yeah.

32:30 **Interviewer:** Well, yeah...

32:31 **DP1:** My general health, my sugar levels I would think, really.

32:33 **Interviewer:** Um, give it, give it some thought again in between the interviews and think of it not only now but what if say, your, your, ur, blood sugar started to go back up if that would change

anything. And, I mean, what, what to consider is what would you want to monitor but also if that data was getting passed on to someone, who would you want to see that data? Who would you want help from?

32:56 **DP1:** Well, it would be my doctor, initially.

32:58 **Interviewer:** Mmm. Mmm.

32:59 **DP1:** Yeah. Yeah. That's something else as well, that data. I'm worr-, well, I'm not worried but I'm just thinking, what if it's collected and things come up...because people make mistakes. (laughter) And it just doesn't get passed on and you'd think you're not safe because you've all this information, all this data collected using all the triggers there, something would perhaps show. So, I presume if, if things...I don't know, say I'd shows signs I was gonna have a heart attack or something like that. I presume that kind of information would then go to my doctor, would it? Or would it just be the general information that's collected or...

33:40 **Interviewer:** He could, he could get all sorts of things. He could get the raw data. He could get a summary of your health over say, last month. He could get emergency alerts although, more than likely that would go to some sort of call center so that they could get someone out immediately. But he may get a report that said that she had an emergency, you know.

33:57 **DP1:** OK. It's just that I'm thinking. I mean, it sounds good to collect all this data, to be able to monitor your condition and control it. But whether it's actually going to work, I think...I don't know whether it will actually be a benefit...

34:14 **Interviewer:** Mmm. Mmm.

34:14 **DP1:** ...other than perhaps, I don't know. Perhaps for somebody in the future to help cure, well not cure. I don't know whether you could cure it or not but whether you could actually minimize it. Do you know what I'm saying?

34:28 **Interviewer:** Yeah. I think I do.

34:29 **DP1:** It's like a research, or cancer research (incomprehensible) get more and more information from different people and eventually they find a new drugs to sort things out. So, is it doing in that direction as well or?

34:39 **Interviewer:** The data could be sort of aggregated and used to, to improve health research. Certainly. Yeah.

34:47 **DP1:** I just wondered what...whether it would be worthwhile.

DP1 - Second Interview

00:01 **Interviewer:** All right, I suppose the first thing would just be to give you an opportunity to talk about anything that you-, that may have come to mind since we last spoke.

00:11 **DP1:** Uhh, only about-, the thing you were talking about, which I wasn't sure about at the time, is the thing on the-, in the house, on the wall or something.

00:20 **Interviewer:** Right, the sensors on-

00:21 **DP1:** Yeah. I didn't understand why I objected to that.

00:24 **Interviewer:** Right.

00:24 **DP1:** But, I think what it is, is if it's something that's attached to my body, then it concerns me, and that's fine because I'm happy with that. But, if it's up somewhere else, it might not have anything to do with anybody else.

00:37 **Interviewer:** Mm.

00:37 **DP1:** But, it appears to. So, I'm intr-, I feel that I would be intruding-, it would be intruding on other people's privacy, and they might feel uncomfortable with it.

00:49 **Interviewer:** Right.

00:51 **DP1:** So, I don't know if that helps. Because I couldn't understand why I felt the way I did last time about having something on the wall. And, I think it is about that. When it's-, when it's on me it concerns me, umm, and has nothing to do with anybody else. So, if it's up on the wall

01:09 **Interviewer:** So, it's almost as if you feel that you're imposing yourself on them?

01:11 **DP1:** Yes. Yes. And, yeah. And they may-, I wouldn't want people to come here, and even though it has nothing to do with them, it would be still monitoring just me, wouldn't it?

01:23 **Interviewer:** Mm-hmm.

01:23 **DP1:** I-, I wouldn't want them to feel uncomfortable about it. Do you know what I mean?

01:29 **Interviewer:** Right.

01:29 **DP1:** So, yeah. So, I think that intrudes on other people. So, I would prefer, for myself, if it was something to be just for me. Something that just I've given permission for. (coughs)

01:44 **Interviewer:** Just to clarify, umm, if the sensors were more or less invisible in the house, so for example, you had a mat beneath that carpet that picked up if someone walked on it. Or, if you just couldn't see them when you walked into the house. Would you still feel that way? Would you still feel like you were imposing on the person?

02:05 **DP1:** Yeah. Yes I think I would.

02:07 **Interviewer:** So, it's not just that they see it when-

02:09 **DP1:** No. No. I've-

02:10 **Interviewer:** -they come in. It's that you've-, you know it's there.

02:11 **DP1:** Yes. Yeah.

02:14 **Interviewer:** You feel it's wrong.

02:15 **DP1:** Yes. But giving permission to monitor me personally, that part's totally fine. But-, yeah, but if it was any way, even if the other person couldn't see it, I just feel that's intruding on their-, their privacy. Although it would have nothing to do with them-

02:33 **Interviewer:** Right.

02:34 **DP1:** -I still feel that.

02:35 **Interviewer:** I think we talked last time about a RFID tag that you could wear, so sensors would just pick you up.

02:42 **DP1:** Yes. Yes.

02:43 **Interviewer:** Again, would that make any difference-

02:45 **DP1:** Not-

02:45 **Interviewer:** -would you still feel like you were imposing on them?

02:46 **DP1:** No, because they wou-, it would-, that's it-, I don't know, it's just this thing to do with me completely, then-

02:55 **Interviewer:** Right.

02:56 **DP1:** -do no-, and it wouldn't have anything to do with then? I know the things around wouldn't be picking up anything from anybody else. But, I would still feel that it's an intrusion.

03:10 **Interviewer:** Oh, so I see. So, you're saying even if the sensors were calibrated to only pick up you-

03:15 **DP1:** Yes.

03:16 **Interviewer:** -if they were still turned on while someone else was in the house, you would still feel that you were imposing on them?

03:21 **DP1:** Yes. Yes.

03:23 **Interviewer:** OK. OK. Umm.

03:25 **DP1:** Whether than makes sense or not, (laughter) I don't know, but that's how I would feel, yeah.

03:29 **Interviewer:** So that-, that's the case on the sensors, don't automatically pick up other people. But then, if you were to have, again, a tag that you wore that just told the sensors, basically, 'Hey,

it's me. Pick me up and nobody else.' Would you then be OK with it, or would you still feel that you were imposing on them? So, it's not-, it's not-, it's not the the tag-. Just to be very clear, it's-, it would be like a card that you would have-

03:53 **DP1**: Yes. Yes.

03:54 **Interviewer**: It's not that the card's doing anything. It's just, it-

03:58 **DP1**: Yeah.

03:58 **Interviewer**: -lets the sensors know who you are.

03:59 **DP1**: Yeah. I-, I think-, I don't know. I just feel if it's on my person, it's fine. If anything is anywhere else, then I don't feel it's fine. And that I can't-, the only thing I can think-, really explain is because then it seems to, even though it might do, it seems to involve other peoples.

04:22 **Interviewer**: Mm-hmm.

04:23 **DP1**: And, I don't think that's right for me to-, I wouldn't feel comfortable with that.

04:29 **Interviewer**: (cough) Would you-, do you feel the same way about Paul? If-, if it's-, in other words, does he count as som-, as-, as an equal someone else in this situation or is it-

04:42 **DP1**: (laughter) No. [interruption]

05:07 **DP1**: Yeah, I'll see you later. (speaking to **Interviewer**) I think really, I would ask him how he felt about it first.

05:13 **Interviewer**: Right.

05:14 **DP1**: And then if he said he wasn't bothered, then I'd be OK with it.

05:17 **Interviewer**: Right.

05:17 **DP1**: But, I think that's the other thing, as well, you can't ask other people how they feel about it, yeah.

05:23 **Interviewer**: So, before you had it installed then-

05:24 **DP1**: I would ask Paul first. I wouldn't just say, 'Yeah, he's all right.' No, I would have to

05:28 **Interviewer**: OK.

05:28 **DP1**: 'Cause I'd feel more comfortable about doing that. (coughs)

05:31 **Interviewer**: Would you, would you, umm, feel the same about other people? Let's say, for example, you have friends and family that come over here on a regular basis, umm, but you weren't able to ask them before you had it installed. Would you just not have it installed for that reason, or would you then ask them if it was OK before they came in the house?

05:50 **DP1**: No, I wouldn't have it installed-

05:52 **Interviewer:** Would you-

05:52 **DP1:** -until I thought they were all right. But, even then, there are an awful lot of people to ask then.

05:57 **Interviewer:** Right.

05:57 **DP1:** So, I probably would-, I don't know. (coughs) I suppose my very close family, I would ask first. Then, you're always-, yeah, people who just come. Say, like yourself for instance someone whose come-

06:13 **Interviewer:** Mm-hmm. Someone you can't know is coming.

06:15 **DP1:** (coughs) Yeah. Yeah, I suppose. I would-, yeah. That-, that's one of the things-, issues I have, really. It-, it seems to involve other people. You don't know how they feel about these things, you know? I consider other people. But, I've-, I've-, so yeah, I play people would feel uncomfortable, if you could switch it off, then that would be not so bad.

06:44 **Interviewer:** Mm-hmm.

06:44 **DP1:** But, would-, would you be able to do that? But then, with the equipment, would you be able to do that?

06:48 **Interviewer:** Theoretically you could, yeah. Yeah. I can't imagine why that wouldn't be included as a feature. I mean, it does in some way undermine the integrity of the data it would be collecting, because it's not over-, it's not all the time, but still-

06:57 **DP1:** Yeah, well, yeah, yeah, yeah, yeah.

07:02 **Interviewer:** -I think. I mean you can tell me if this sort of matches up with what you're thinking, but I think there is-, it's quite important to have the choice to disconnect.

07:11 **DP1:** Yeah.

07:12 **Interviewer:** You were kind of saying that last time, about the clothes.

07:14 **DP1:** I think-, yeah-, I think that's how I would feel really, then-, because then I could make a decision. Or, if somebody really, umm, if I thought somebody would object to it, I could switch it off.

07:26 **Interviewer:** Yeah.

07:27 **DP1:** Yeah. I think you need a little bit of control over it, really.

07:30 **Interviewer:** Yeah. That-, that was definitely, when we spoke last time, that was a sticking point that you kept bringing up. That the clothes, you felt like you could take them off and that was it.

07:38 **DP1:** Yeah.

07:39 **Interviewer:** But, the house-

07:39 **DP1:** Yeah. And that's still how I feel, I think.

07:42 **Interviewer:** Right.

07:43 **DP1:** Yeah, I'm not the sort of person that likes to be controlled. You know what I mean? I like to know what I'm doing, be able to sort things out.

07:52 **Interviewer:** Right.

07:52 **DP1:** Yeah. So, I think control would be an issue for me.

07:56 **Interviewer:** Right.

07:56 **DP1:** (coughs)

07:58 **Interviewer:** (pause) Hmm. (pause) Let's see, we spoke about, we spoke about lots of stuff. One other thing that you mentioned last time, about the technology in the house, umm, you used the term 'Big Brother'. You also said that it was unsettling.

08:17 **DP1:** Yes.

08:18 **Interviewer:** Umm, and just the fact that it's in your house would bother you. One thing you said was, that you wouldn't feel like it was in your control if it was in your house.

08:30 **DP1:** Yeah.

08:30 **Interviewer:** Do you still-, you still feel that?

08:31 **DP1:** Yeah, that's one of the thing-, that's what I'm saying. If you could switch it off, then you have got control.

08:37 **Interviewer:** OK.

08:38 **DP1:** But if it's just there all the time-, see, I'm not quite sure exactly what's going to happen to the data. So, the data all gets collected-

08:48 **Interviewer:** Mm-hmm.

08:49 **DP1:** So, what happens-, I know you could-, it goes to the doctor, but-, I don't know quite how to phrase it. Say it picked up something that was of concern, and I ought to be seeing my doctor because I'm not sure exactly what the data is that's going to be collected. Say it picks something up, but, does that get reported to my doctor straight away, or to me? Or does it just sit somewhere and nobody does anything with it?

09:17 **Interviewer:** Well there's no-, there's no one way that the data is handled, because it's going to depend on-

09:22 **DP1:** OK.

09:22 **Interviewer:** -the specific technology-

09:24 **DP1:** OK.

09:24 **Interviewer:** -and-, and who's using it-

09:26 **DP1:** Right.

09:26 **Interviewer:** -and for what purpose.

09:26 **DP1:** So, is this data just for research purposes?

09:29 **Interviewer:** Not necessarily, it-, it can be for-, I can't say that it's for one specific purpose-

09:36 **DP1:** OK.

09:36 **Interviewer:** -'cause we're not using the technologies yet. I can say that possible reasons that you would collect it would be for research purposes for emergency alerts. So, to detect if you're about to have a heart attack, for example. And to detect patterns in your health. And detecting if you're making yourself healthier, yeah.

09:54 **DP1:** So, if it detected that I was about to have a heart attack, what would happen then, from the other end? Would somebody contact somebody to say that I'm about to have this heart attack. Or will it just sit there and I-, then nobody does anything and I have a heart attack?

10:10 **Interviewer:** Well- (laughter)

10:11 **DP1:** (laughter) That's where I'm coming from. I mean, it's just-

10:16 **Interviewer:** I can't say it will work every-, every single time, but as far as I understand, the purpose of the devices that are being developed with emergency alerts in mind, is that it alerts someone, say, at a call center-

10:29 **DP1:** Right.

10:30 **Interviewer:** -or at, umm, what's the emergency number in this country?

10:32 **DP1:** Nine, nine, nine.

10:33 **Interviewer:** Nine, nine, nine. It alerts-, alerts someone there and so it's almost like it's taking the call out of your hands.

10:38 **DP1:** OK.

10:39 **Interviewer:** It's just-, it-, it's almost as if that's acting as a call to nine, nine, nine.

10:44 **DP1:** OK.

10:44 **Interviewer:** So. It-

10:46 **DP1:** So, there-, it's meant to do that?

10:48 **Interviewer:** Yeah, at least for the emergency.

10:48 **DP1:** For the emergency, it would.

10:49 **Interviewer:** Yeah, for the emergency situations, it's meant to do that.

10:52 **DP1:** OK. OK.

10:52 **Interviewer:** Umm, for the non-emergency situations, it's more-, it's not clear who the data would go to. And actually, that's one thing that would be interesting to talk about, is the data that's not an emergency alert, because that seems pretty clear that should go to the emergency services.

11:09 **DP1:** Yes.

11:10 **Interviewer:** Th-, but the stuff that's not emergencies, that the patterns in your health, which to be fair, is going to be the majority of the data that would be collected. Who do you think that should go to?

11:20 **DP1:** Well, I think it should go to the doctor and to myself. Umm, because otherwise, what's the point of collecting it? The-, all this data? Other than it showing up patterns of things that will go into, so-. It's no good it just sitting somewhere, is it? If it needs to go to your doctor, but you can't always guarantee they will contact you. So, also I would want to see it, because whatever tests I have done, I always have the results, I'm not satisfied with, 'Oh, you're OK now.' I want to know. But, then other people don't do that. But, for me personally-

11:59 **Interviewer:** Right.

11:59 **DP1:** -I would want to know.

12:02 **Interviewer:** What sort of-, of-, this may be a tough question to answer, but what sort of data would you expect to get from the system?

12:10 **DP1:** It depends what they were monitoring, really. Wouldn't it? Because, I mean, for diabetes you are susceptible to strokes and heart attack. To be honest, that's in my family history, anyway. Not diabetes, 'cause I'm the first person, but heart attacks and strokes are. So, I suppose it puts me at a higher risk for that, anyway.

12:28 **Interviewer:** Mm-hmm.

12:29 **DP1:** So, that kind of data would be-, I would-, you know that would be useful. But with having said that, I am being monitored for my blood pressure and all. This is just an extra thing, I'm not quite sure how it would fit in with what I already have.

12:45 **Interviewer:** There-, so, there's a few different ways that the data could be presented to you. I have a couple of mock ups of-, of, umm, the types of read-outs, I suppose, you could get from these systems. I'll show a few of these to you. (pause) 'Cause the question is sort of-, the system is going to be collecting a bunch of raw data about something. So, it could be your, uhh, blood pressure over time, your heart rate over time, your, uhh, blood sugar over time. Umm, but the point is, it's collecting some aspect of your health over time. But, there are different ways to present that, say, to a doctor and to, umm, someone who's actually using the technology. So, you could be presented with, umm, say a bunch of raw data. So, you could be pr-, presented literally with-. This is, this would be a pedometer reading

13:43 **DP1:** Oh. Right. How many, yeah, steps you take in a day.

13:47 **Interviewer:** How many steps you take, and it-, it could get even more fine grain than that. It could be down to the weeks.

13:51 **DP1:** OK.

13:52 **Interviewer:** Or even the days.

13:52 **DP1:** Right.

13:53 **Interviewer:** So, that's just giving you a read-out of all of the data.

13:55 **DP1:** Uh-huh, yeah, yeah.

13:56 **Interviewer:** Same for-, same for weight. And, this one could be used for weight, for blood pressure-

14:02 **DP1:** Yeah. OK.

14:03 **Interviewer:** -yeah, for heart rate. It would show you changes in something over time.

14:07 **DP1:** Yeah. Yeah. Yeah.

14:08 **Interviewer:** Whereas, what you would traditionally have is-

14:11 **DP1:** All right. Yeah.

14:12 **Interviewer:** -a graph that looks like that from the doctor-

14:13 **DP1:** Yes. Yeah.

14:14 **Interviewer:** Which corresponds to when you actually go to the doctor.

14:19 **DP1:** All right, so, it's almost like the blood test, then, for what it is, the H-, is it HBA or HAB1C thing, which can now monitor your blood sugar levels for a three month period, can't they.

14:30 **Interviewer:** Right.

14:30 **DP1:** But, so, this would also-, oh, I see.

14:36 **Interviewer:** Wh-, when I ask-

14:36 **DP1:** You're getting a-, you're getting a better reading at different times-

14:39 **Interviewer:** Yeah.

14:40 **DP1:** -to relate to what you are doing I suppose, as well, at that time, isn't it though, rather than, right?

14:46 **Interviewer:** Well, let's talk about the different types of data you can get. 'Cause you can get graphs like that, which, that is basically the raw data. That's just showing you a numerical value corresponding to a time.

14:56 **DP1:** Yeah.

14:56 **Interviewer:** And, it would show you that over a long period of time. And, what that's doing is showing you fluctuations in-, in whatever aspect your health we're looking at, weight or more heart

rate, or what have you. It could also just be given to you as a report, saying your blood pressure for the month of May was within expected or normal limits, and normal fluctuations. You don't have anything to worry about. Umm, I'm trying to think how else it could be given to you, umm, we have, just as a general report, we have the raw data.

15:34 **DP1:** Two-

15:35 **Interviewer:** I mean, of those two, which one would you want?

15:38 **DP1:** Umm, I suppose, not-, you see, I'd just take anything. (laughter)

15:47 **Interviewer:** Right. OK. (laughter)

15:48 **DP1:** Do you know what I mean? I-, I would be interested in it all, that's the thing. Umm, so, yeah, I mean, I don't think I would be happy with, 'Your blood pressure has been OK for this month.' Uhh, because OK can be top of the OK range, it could be lower.

16:07 **Interviewer:** Yeah, it could be quite a range.

16:08 **DP1:** I'd rather know if it got-, that's what I think I would-

16:12 **Interviewer:** OK.

16:12 **DP1:** And the same. The same, like, with the-, the steps, it would be nice to know how many steps you've done, rather than say, 'Oh, you've done adequate amount of exercise,' or whatever.

16:21 **Interviewer:** Mm-mm.

16:22 **DP1:** For so and so. I prefer (incomprehensible) to a general, 'You're OK.'

16:29 **Interviewer:** Right. I mean as far as the blood sugar, I imagine you would be able to interpret the results pretty easily yourself, 'cause you're already familiar with how to do that.

16:37 **DP1:** Yeah, except I don't test, you see.

16:38 **Interviewer:** Yeah, yeah, yeah.

16:40 **DP1:** I do it at the doctors, but-

16:40 **Interviewer:** Right.

16:40 **DP1:** - but, they give me the actual readings, so-

16:44 **Interviewer:** Right.

16:45 **DP1:** -and I keep a record of it, so I know what it's done, so that's, you know-

16:49 **Interviewer:** So it sounds like you have a history of being interested in the actual figures.

16:52 **DP1:** Yeah, yeah I think it's more important than somebody saying you're OK and don't worry about it. I just like to know, that's all. It means more, I think.

17:03 **Interviewer:** I remember the third way I wanted to show you the data could be presented.
(laughter)

17:07 **DP1:** (laughter)

17:08 **Interviewer:** And this one, you're gonna have to, uhh, use your imagination a bit on this one.

17:13 **DP1:** OK.

17:14 **Interviewer:** So, this would be, say, this would be tracking your behaviors. This is actually a graph of how much time you spend each day watching TV, and how much time you spend outside each day.

17:25 **DP1:** Oh, wow. In and out, OK.

17:27 **Interviewer:** But, the idea would be you could match up that data with your behaviors throughout the day. So, what you ate, what sort of activity you're engaging in, and see how-

17:35 **DP1:** Yeah.

17:36 **Interviewer:** -your activities effect you. Would you-, would you want that?

17:38 **DP1:** Yeah, that would be really interesting. Yeah.

17:42 **Interviewer:** And then, another sort of thing you could get, is this would give you, umm, a list of days where your measurement was in the good range-

17:53 **DP1:** Right.

17:54 **Interviewer:** -and the bad one. And then also a photo of yourself on that day.

17:57 **DP1:** Right.

17:57 **Interviewer:** Or, it could even be, say, a summary of your activity for that day.

18:01 **DP1:** OK.

18:01 **Interviewer:** And in some way, that's going to-, I suppose the point of giving you that is to influence-

18:08 **DP1:** I would say, yeah, go on, I'm sorry.

18:11 **Interviewer:** Oh yeah, it's to influence your behavior in some way, or it's supposed to be information that you could use to your own benefit.

18:18 **DP1:** Yeah.

18:18 **Interviewer:** Wha-, what are your thoughts on getting that sort of-

18:21 **DP1:** Now, I would like that. Because sometimes you think you've done things, or-, and when you actually stop and really think about what you've done, you haven't done what you think you've done.

18:31 **Interviewer:** Mm-hmm.

18:32 **DP1:** Uhh, and people always overestimate what they do. 'Cause I used to, well, believe it or not, I used to be quite physically active. I used to do triathlons and things. And when you turn to people and say, 'Oh, I did around so and so, so many miles,' only when they tell you where they went, you think, 'You didn't do that far.'

18:51 **Interviewer:** Right.

18:51 **DP1:** You know. People overestimate all the time and sometimes you think, oh, I've walked every day this week, but you've forgotten Thursday, or-

18:58 **Interviewer:** Mm-hmm.

18:59 **DP1:** -do you know what I mean?

19:00 **Interviewer:** Yeah.

19:01 **DP1:** So, if you've got that kind of data, it makes you think about it a little bit more. And it makes you think, 'Well, I'm not actually doing enough, perhaps I should do a little bit more, or more of that.'

19:11 **Interviewer:** So, you do like the idea of having your behaviors monitored and reported to you.

19:15 **DP1:** I-, well, in that way, yes. I mean, but that could be done on my body rather than-. But, I suppose you've got to have sensors in the house.

19:24 **Interviewer:** There'd have to be some sensors in the house for that, yeah.

19:27 **DP1:** Yeah. Yeah. Mmm. I suppose I would come round to it, actually. It's because it's a new idea, and you think about these things, perhaps, and it may not actually be as intrusive as I feel it might be. It was just that when you said it, ooh, ooh, you know, that you do. Umm, so yeah. So, I suppose you would have to-

19:52 **Interviewer:** Yeah. Yeah.

19:53 **DP1:** Yeah. Yeah. Hmm.

19:55 **Interviewer:** I'm curious, umm, right now we've been talking about you getting the data on your behavior and on the aspect of your health and the two being matched up so you can read through it. Umm, would you want your doctor to have that information as well, for you?

20:11 **DP1:** Yeah. Yeah.

20:11 **Interviewer:** You would. So you-, you'd be OK with him, say, knowing that on 3 pm. on Tuesday, you were outside having a walk, but then, you came back and sat on the couch for two or three hours?

20:20 **DP1:** All evening. (laughter)

20:22 **Interviewer:** Yeah. (laughter)

20:24 **DP1:** Well, yeah, because he's treating me, he's trying to make me better. Uhh, what's the point of him not knowing what I'm really doing?

20:31 **Interviewer:** Right.

20:32 **DP1:** So, I'm happy with that. But I can see a lot of people wouldn't be, because I know a lot of people who pretend they're doing stuff for their doctor. Like somebody the other day, from the diabetes thing, said, 'I'm trying to lose weight quick because I'm going to the doctors for my annual review.'

20:50 **Interviewer:** Mm-hmm.

20:50 **DP1:** And I thought, 'Well, when they do your HAB1C thing, they're gonna know what you've been doing for the past three months anyway.'

20:56 **Interviewer:** Yeah.

20:56 **DP1:** Because they do. So, what's the point? You might as well be doing that all the time. And that, for me, I think this would be quite useful. But, I could see for other people, that they wouldn't use the information even.

21:10 **Interviewer:** So, are you typically very honest with your doctor when you go and see him?

21:14 **DP1:** Yeah, if I can be. Yeah. Yeah.

21:17 **Interviewer:** I think that might be rare in itself, to be completely honest.

21:20 **DP1:** Yeah, well there's-, there's no point in telling him you do something and you don't. 'Cause at the end of the day, he's gonna know-

21:28 **Interviewer:** Mm-hmm.

21:28 **DP1:** -from your results. So, you know, he's there trying to make you better.

21:33 **Interviewer:** Mm-hmm.

21:33 **DP1:** And, but like-, yeah, I think you are right, actually. A lot of people don't. A lot of people-, I mean, they know what's wrong with them, but they eat stuff they should never eat.

21:42 **Interviewer:** Mm-hmm.

21:42 **DP1:** And that-, I see it, I see it all the time. And it doesn't-

21:45 **Interviewer:** we're imperfect. (laughter)

21:47 **DP1:** (laughter) Yeah. Yeah. So.

21:51 **Interviewer:** So, it sounds like you're OK with the-, the GP having access to it.

21:54 **DP1:** Yeah.

21:55 **Interviewer:** Umm. What about-, I'm trying to think who else would have access to it. Uhh, the-, again, the behavior and the health data combined. NHS? The-, the organization in general, and it could be passed around the NHS and used for research purposes, demographic-

22:14 **DP1:** Yeah. I presume it would be anonymous and-, or well.

22:18 **Interviewer:** With-, with your GP it wouldn't.

22:19 **DP1:** Well, no. Not with my GP.

22:20 **Interviewer:** But, you would want it to be anonymous when it gets passed on?

22:23 **DP1:** I think so, because you-, then, you don't know who's looking at it. But if it's-, because if it's being used as research, it's just a person doing this, isn't it?

22:34 **Interviewer:** Mm-hmm.

22:34 **DP1:** 'Cause at the end, NHS in general, wouldn't really have anything to do-, do you know what I mean?

22:39 **Interviewer:** Well, what-, what they might use the data for is, say, demographic information, research, and also, uhh, figuring out what sort of services they need to offer. within a region.

22:49 **DP1:** Yeah. But they don't need to know who I am for that.

22:51 **Interviewer:** Right.

22:51 **DP1:** Do they?

22:53 **Interviewer:** Uhh, presumably not, no.

22:55 **DP1:** No. No.

22:57 **Interviewer:** Uhh, so-, but let's say they did, I mean, what sort of, it-, before you said, 'Yes, it's OK to give them my personal details,' what information would you need? Like, with your GP, you have some idea of what he's going to use the data for.

23:11 **DP1:** Yes.

23:12 **Interviewer:** What do you -, what would you need to know before you were happy giving someone-

23:16 **DP1:** I mean, I don't think it matters, uhh, really, that anybody in the NHS has my details, personally. In-, also, in general, other people, other people might object to-, 'cause I mean, it's just an illness at the end of the day.

23:34 **Interviewer:** Mm-hmm.

23:35 **DP1:** But seem to think that it's, umm, I don't know. They-, they seem to think that it's-, ohh, it should be (whispering) a quiet thing. You know, a secret thing. But it is OK, like the time it's self inflicted. But people won't face up to that. I think they think it's, you know-, so, yeah. I don't think I actually object to them, I just wondered, umm, you know, why they would need my personal details,

really. 'Cause at the end of the day, you need the research to be able to find ways of dealing. Yeah. Yeah.

24:17 **Interviewer:** (pause) Considering what to-, to talk about next. But, while I do that, I brought, just so you can actually see the sort of thing we're talking about, I brought some pictures of the, of the sorts of things that you could wear.

24:33 **DP1:** All right. OK.

24:35 **Interviewer:** Yeah. (pause) The smart shirt that I showed there, that's one that was developed for the military.

24:43 **DP1:** I was going to say, 'There's no way I could wear that.' (laughter)

24:46 **Interviewer:** (laughter)

24:47 **DP1:** I have these funny turns, which I'm having now, actually, all right, where I get really, really hot, it's one of the problems. I can't-, I couldn't possibly wear anything like that. The wrist thing's OK. (laughter)

25:01 **Interviewer:** (laughter) Yeah.

25:02 **DP1:** That's fine.

25:04 **Interviewer:** That-, that is just an old prototype.

25:03 **DP1:** Yeah.

25:06 **Interviewer:** They're thinking that they will be able to imbed it, just in normal clothing.

25:09 **DP1:** Yeah.

25:11 **Interviewer:** Yeah. Because, what happens often is these types of technologies are developed for the military first.

25:16 **DP1:** Yes. Yes. Yes.

25:16 **Interviewer:** And then translating into civilian use. So, there were two things that I asked you to consider last time, I just want to return to. One, we've been talking about.

25:27 **DP1:** Yes.

25:27 **Interviewer:** It's where would you want the data to go to, and who would you be comfortable having it. But, you brought up an interesting issue last time I hadn't considered actually. And, that's if-, if you-, if your data is being collected, the systems are in some way giving you a sense of security, or the sense that you're being taken care of. But you brought up that you don't actually know that your data is actually being looked at by anybody.

25:54 **DP1:** Yeah.

25:54 **Interviewer:** It's just giving you that-, that sense of security.

25:57 **DP1:** Yeah.

25:57 **Interviewer:** Do you think that would in-, effect you actually using the technologies at all? Can you think of a way that-, that worry would go away? Something you could do to-

26:07 **DP1:** Oh. Well, if you're given-, if you're going to be given things like this, then you know that something's being done with whatever it is. It is only information coming back to me myself, and the general picture of my health. At least you know something's happening, but if you were just wearing it, and it goes off somewhere, what happens-, that you know, you feel, what's the point of wearing it? Why? You'd want some kind of feedback from somewhere. But, then these will be giving you it, wouldn't they?

26:37 **Interviewer:** Those could be produced by the machine itself, though.

26:40 **DP1:** Oh. Right. So, nobody else is looking at-. Yeah, but having said that, even if they were through just the machine, I would be getting information, so if I saw something I was concerned about-

26:52 **Interviewer:** So, it is more important to you to have the feedback yourself or to have the monitoring done so that your doc-, you know that your doctor knows more about your condition?

27:03 **DP1:** Umm, (phone rings) I'll leave that, it will be OK. Umm, both I think.

27:09 **Interviewer:** They're both equally important to you?

27:10 **DP1:** Yeah. Yeah.

27:12 **Interviewer:** How-, can you imagine how your doctor having that information-, again the behavior information, the health patterns over time. So having quite accurate and far more information that he would have otherwise, about your health. Can you think of any way that that might change your interactions with him, or your relationship with your doctor?

27:31 **DP1:** Umm, no I don't think so. I think, umm, if he's just got more information, hasn't he? So, he can make-, he can make better judgments, maybe. I mean, from my-, from my point of view, I'm quite open. Yes, that's really funny, because from my point of view I would tell him everything he wanted to know, if he asked me questions. For them, it might be better if their doctors got all that information for treatment and things.

28:04:52 **Interviewer:** Mm-hmm

28:04 **DP1:** So, this kind of information that he's got-

28:06 **Interviewer:** Wouldn't that sort of be taking the decision out of their hands, though?

28:11 **DP1:** Yeah. So, that's not ethical, either. (laughter) So, if I was in that category of people, I would fee, 'No, I don't want anything to do with that, 'cause I've got not control over it and why should we be doing it?' So, I don't know. I don't know that he would, really, because he does all the tests, and he makes lots of judgment on it, really.

28:32 **Interviewer:** Mm.

28:32 **DP1:** When I think about it. And-, but, on that point, now where, every so often, I don't see him so much anyway. But he-, obviously, he does have access to all sheets I needed to see.

28:45 **Interviewer:** One worry that's been expressed by doctors over this sort of data being given to patients, is that it can make patients take-, I mean, of course they're already responsible for their own health, but sort of take their care into their own hands and possibly make bad decisions based on the data.

29:04 **DP1:** Yeah.

29:05 **Interviewer:** Umm, do you think that's a legitimate worry?

29:09 **DP1:** Yes.

29:09 **Interviewer:** Do you think it could lead to any bad consequences for yourself if you have the data?

29:13 **DP1:** No, 'Cause if I was concerned about it, the first thing I would do is go to the-

29:15 **Interviewer:** Right.

29:15 **DP1:** But I can see other people would go-, and, and, I don't know. But, people have the picker machines now, testing their own blood, and they don't do anything with it. When their, you know, when their blood sugar levels are really high-

29:31 **Interviewer:** Mm-hmm.

29:32 **DP1:** -they don't alter their behavior or their, uhh, medication or anything. They just record it and do nothing. So, I think they would be exactly the same with that.

29:42 **Interviewer:** You don't think having your health data in real time would actually change that-, it wouldn't lead to changing behaviors at all? Because, again-

29:50 **DP1:** It would for-, it would for me. Because, if I thought something wasn't right, then I would do something to see that it was right. But I would see my doctor, umm, it depends on what it was, of course. I mean, umm, but I would talk to my doctor about it. But then I could see that other people wouldn't.

30:11 **Interviewer:** Because, you could make the argument, and this may be an argument that would be made my doctors, is that the type of data that I've showed you, the behavior and the health data over time, should only be given to the doctor to avoid patients making bad decisions on their own. For example, if you had your weight in real time, or you had your blood pressure in real time, and you saw that it was going up. Whereas that may be just a normal fluctuation, which you wouldn't detect without these sensors

30:43 **DP1:** OK.

30:43 **Interviewer:** Umm, you may then alter your behavior, thinking, 'Oh- (recording stopped then restarted)

30:46 **Interviewer:** Oh, there we go. Sorry about that. (laughter) Yeah, so we were saying-

30:53 **DP1:** You were saying about the weight going up. But then, people do that anyway, don't they? People weigh themselves and people know when they're putting on weight, so they-

31:01 **Interviewer:** But, I suppose that the reason the doctors would say that is, now you suddenly have real time data about your health at all times, so it could really increase the opportunities to take bad decisions, or bad behaviors that may not benefit your health in the long run. So, the argument would then be, that only the doctor should have access to it so that he can give you healthy recommendations, things that will actually help you, rather than things that will just make your blood pressure temporarily go down.

31:27 **DP1:** But do you think, from my point of view, that would be, like, losing a little bit of control. I can see-, I can see where they're coming from if that's what they would be-, if they did that.

31:38 **Interviewer:** I-, I can't say for sure that-

31:41 **DP1:** Well, I'm not saying that they are, no, but I'm just thinking it through. If they did come back and say that, I could understand that, actually. Umm, but, then I'd prob-, for me personally, I'd probably go and say to my doctor, 'Look, I like that sort of-, I liked and that I've got control.'

31:59 **Interviewer:** Mm-hmm.

31:59 **DP1:** But, so he'd probably give it to me, so I would probably have to go to him to get that information rather than just get it, yeah.

32:05 **Interviewer:** Right. But, it would make you uncomfortable for just the doctor to have it?

32:10 **DP1:** For me, personally, yeah, yeah.

32:13 **Interviewer:** Yeah.

32:13 **DP1:** 'Cause I've been given a lot of information and I've adjusted my life to that information I've been given.

32:20 **Interviewer:** Mm-hmm. Right. Umm, the very last thing that I want to ask, then, is another thing that I asked you to consider, and you did start to answer the question last time. Was if you could one of the devices for free, what would you want it to do? And would want it to not do? And, your initial reaction was just to monitor your general health and your, uhh, and your blood sugar levels and also your exercise.

32:45 **DP1:** Yeah. 'Cause-, umm, yeah-, if it-, it's really interesting like if it can monitor your blood pressure, umm, which gives you, uhh, a good indication. 'Cause it-, like I said to you before, heart attacks and strokes are probably a bit of a concern for me.

33:02 **Interviewer:** Mm-hmm.

33:02 **DP1:** So you know, things that would give me indications that this was, you know, umm (laughter) not that I'm about to suddenly keel over, but if things were starting to slip, umm, because that does happen. Although, you-, you think, you know, you take all this exercise and you keep your

food as it should be. Little things do slip, and you suddenly think, 'Oh, I'm doing bad. And I don't ought to be, really.'

33:29 **Interviewer:** Mm.

33:29 **DP1:** And you go back. And this just gives you a little reminder, all this-, that kind of information. But if it monitored your blood sugar, and you-, what other things would it be able to monitor?

33:42 **Interviewer:** Umm.

33:41 **DP1:** Your exercise level, I suppose.

33:44 **Interviewer:** Yeah, the exercise, your diet, uhh, your body temperature, your-, I heard of one the other day that could, I think it was an implantable one, but it could actually measure, umm, if cancer was starting to develop.

33:58 **DP1:** Oh, now, see that's interesting.

33:58 **Interviewer:** I think that one's still an experimental idea.

34:01 **DP1:** Yeah.

34:02 **Interviewer:** But, it was very much a device that is implanted in you and then monitors if there's-, it's-, it's something that appears in your blood when you start to get cancer, when the tumors start to grow.

34:12 **DP1:** Yeah. Yeah. Yeah. So, they can detect a lot of different kinds of cancers through your blood, you say?

34:18 **Interviewer:** Yeah.

34:18 **DP1:** So, yeah. Yeah. See, I would be interested in all that because then I know it's going to be spotted quickly. Because that's the route to everything really, if you treat-, if things are found quickly and dealt with quickly, they're not such a problem.

34:30 **Interviewer:** Mm-hmm.

34:33 **DP1:** I-, I yes, I would be interested in anything.

34:37 **Interviewer:** That's actually is something I hadn't considered asking is, would you be-, 'cause that's actually going a step further, it's saying, 'We're going to implant something-'

34:43 **DP1:** Yeah.

34:44 **Interviewer:** '-to monitor your health.' Would you be OK with that?

34:45 **DP1:** I took-, I took that little statement on board and thought, 'Mm, what do I think about that?' But, having said about the cancer, I don't want cancer again.

34:55 **Interviewer:** Mm-mm.

34:55 **DP1:** That would be awful. And I think I would-, on-, without having given it a lot of thought, my initial thought is I think I would because, that, cancer's in my family as well. So.

35:07 **Interviewer:** Right.

35:08 **DP1:** Yeah.

35:08 **Interviewer:** Umm, suppose all (incomprehensible) an unfair question. Privacy is a very complex, uhh, complex idea. Uhh, a lot of facets to it. You said earlier that if someone came into your house and you had the devices in here, you would feel like you were intruding on their privacy. What-, how were you thinking of privacy at that point? Like, what do you mean by their privacy?

35:33 **DP1:** I-, I, ah, it's because, I don't know. I just feel I can say whatever I have done for myself is absolutely fine, but even if these things don't monitor somebody else, I don't know how they, personally, would feel about it. So, like my first reaction, when you said about the sensors in the house, was to back off.

35:59 **Interviewer:** Mm-hmm.

36:00 **DP1:** That's how other people may well feel. And they may feel more strongly about it than me. So, they would be uncomfortable. It's not whether it has any real effect on them, I wouldn't want them to come here and feel uncomfortable.

36:16 **Interviewer:** Is it that you don't want to take the choice away from them-

36:20 **DP1:** Yes

36:20 **Interviewer:** -to be monitored or not?

36:21 **DP1:** Yeah. Definitely.

36:22 **Interviewer:** OK.

36:23 **DP1:** Because I don't think I have a right to do that.

36:25 **Interviewer:** Right.

36:25 **DP1:** They have to give their own permission to do that.

36:28 **Interviewer:** OK.

36:28 **DP1:** Absolutely.

36:29 **Interviewer:** OK. OK.

36:29 **DP1:** So, I-, I suppose I'm very concerned about other people's privacy. Not so concerned about my own.

36:35 **Interviewer:** Right.

36:35 **DP1:** Because, I'm not that worried about it. I don't mind-, what I've got or what I've had or, but other people are. And I know that other people are. So, I would-, I wouldn't want anything to make other people feel uncomfortable.

36:46 **Interviewer:** Right.

36:47 **DP1:** So, that's where it's coming from, I think.

36:49 **Interviewer:** It almost sounds like, if I can summarize it, it almost sounds like you're saying, umm, you realize that the technology intrudes on your privacy in some way.

37:03 **DP1:** Yeah.

37:03 **Interviewer:** But, you're making a conscious decision to say, 'OK, I realize it's intruding on my privacy, but I'm still going to use it because of the benefits.'

37:10 **DP1:** Yeah.

37:11 **Interviewer:** And you don't want to take that choice away from people entering your house.

37:15 **DP1:** That's right.

37:15 **Interviewer:** Is that-,

37:16 **DP1:** And that's exactly, exactly, yeah.

37:17 **Interviewer:** OK.

37:18 **DP1:** It's OK for me to make that decision for myself.

37:20 **Interviewer:** Right.

37:21 **DP1:** And even if they knew it was only monitoring me, they might still feel uncomfortable with it. That-, that's the issue.

37:29.02) **Interviewer:** OK. All right, great. Well, yeah, that clari-, that clarifies what you meant by privacy.

37:33 **DP1:** Yeah.

37:34 **Interviewer:** Unless-, we'll end there unless you have anything else that you want to-

37:38 **DP1:** I think-, I think that's, umm, I've got a better understanding of it, as well, now, knowing some of the data, how it can be presented and what I can do with it if I had that information.

37:47 **Interviewer:** Right.

37:48 **DP1:** You know, yeah, 'cause that was another concern, what was going to happen to it, or when it was-

37:53 **Interviewer:** Right.

37:54 **DP1:** I can see that I could actually have access to it as well, that's-

37:57 **Interviewer:** Right.

37:58 **DP1:** Yeah.

37:59 **Interviewer:** So, you-, you found the pictures then, of the data, helpful?

38:03 **DP1:** Yeah, 'cause I think- Well, you know, before I wasn't sure how much data I could have, what it was actually measuring, and things like that. But, now I've got a better picture of that.

38:12 **Interviewer:** OK.

38:13 **DP1:** For me, personally, it would-, I'm fine with it.

Appendix 17: Published Works

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ETHICAL ISSUES OF PERSONAL HEALTH MONITORING: A LITERATURE REVIEW

By Brent Mittelstadt, Ben Fairweather, Mark Shaw, Neil McBride

1. Abstract

Personal Health Monitoring (PHM) technologies are currently in development to supplement medical care environments with health monitoring outside “brick and mortar” settings to better meet the needs of people with long-term illnesses. This review identifies common themes in the current literature discussing ethics of PHM and gaps in need of further research. Identified themes include privacy, autonomy, medicalization, social isolation, visibility and impact on healthcare providers. An in-depth discussion of the ethical issues of PHM was rarely found in the searched literature. Areas in need of further research include inadvertent monitoring and the impact of PHM on families and patient relationships.

2. Introduction

Personal Health Monitoring (PHM) technologies are currently being developed to supplement medical care environments with health monitoring outside “brick and mortar” settings. A primary factor spurring the development of PHM is the rapid aging of the global population which is predicted to increase the burdens placed on many countries’ healthcare systems, potentially outstripping available medical resources (Agree et al., 2005). Although the elderly are a primary force behind PHM, systems are currently in development for a multitude of audiences of all ages and health. This paper provides a review of the literature relating to the development and implementation of PHM technologies that discusses ethical issues.

In the current literature agreement upon a common definition of “Personal Health Monitoring” does not exist, with many synonymous and related terms being used instead including “telecare,” “assistive technologies,” “ambient intelligence,” and “wearable health sensors.” For the purposes of the current review a working definition was established that incorporates the related terms: Personal Health Monitoring refers to any electronic device or system that monitors a health-related aspect of a person’s life on a constant basis outside of a hospital setting. Recently developed examples include GPS tracking devices used with mental health patients, blood pressure wrist monitors and “smart clothes” capable of measuring physiological signs (Stergiou and Bliziotis, 2011, Lymberis, 2005, Lauriks et al., 2007). PHM devices may have the capability to record data both locally and offsite, or to register an alert in the case of abnormal activity; however, these optional features are not necessary to designate the technology as PHM.

Although the ethical discussion of PHM is still nascent, implementation is already occurring in the homes of elderly people (Zwijssen et al., 2011). This early deployment is partially due to the recognition of the health benefits of ageing at home instead of living in a care facility (Bowes et al., 2011). Unfortunately, monitoring of any type tends to raise questions about privacy, autonomy and independence. When considering these two factors together an in-depth discussion of the ethical issues raised by PHM is both necessary and appropriate at present. To spur this discussion a literature review, to identify common themes within the debate on the ethics of PHM, was conducted.

3. Method

Academic literature available in four databases (Scopus, IEEE, MEDLINE, and CINAHL) addressing the ethical implications of PHM was reviewed over a period of several months. Attention was given to the discussion of ethical issues in each article, with the goal of identifying the themes present in the literature. The databases were searched to identify literature discussing ethical issues relating to development and implementation of PHM technologies. The search was limited to English language articles. No date restrictions were placed on the search, but all results happen to be from 2003 or later.

3.1 Procedure

Articles were located from May 2010 to June 2011 by systematic searching of databases as well as manual journal searching, citation tracking from found papers, and presentation of papers by research colleagues. Recognizing that “Personal Health Monitoring” is an emerging term not yet widely used in the literature, synonymous and related search terms were employed during database searches including “wearable body sensors,” “personalized health,” “pervasive health,” “assistive technologies,” “health surveillance,” “ambient assisted living,” and “smart homes.” All articles matching the synonymous terminology were checked to ensure the technology under discussion matched the working definition of PHM.

Search queries consisting of three categories were employed. The first category included “personal* health* monitor*” and related terms, while the second category used broader information and communication terms such as “ubiquitous computing” and “ambient intelligence” linked to healthcare or medicine with the “AND” Boolean operator. The first two categories were combined using the “OR” Boolean operator. Finally, the third category was a single term: “ethic*” linked to the first two categories with “AND.” The desired outcome of the search query was to identify articles directly mentioning PHM or related terms that also directly discussed ethics or ethical issues.

This method was intentionally chosen to identify articles explicitly addressing ethical issues of PHM and to limit the quantity of results. Prior literature reviews on specific ethical issues within PHM involving surveillance technologies and residential or community elderly care settings have used more inclusive search terminology and provided analysis of articles and themes not explicitly addressing ethics, but still involving well-recognized ethical issues such as privacy and autonomy (Zwijssen et al., 2011, Niemeijer et al., 2010). After piloting the database searches including these and similar terms, it was determined that their inclusion resulted in too many irrelevant articles being returned.

Articles were reviewed to determine relevance to the current review. Articles were excluded if they only discussed development, implementation or technical specifications of PHM technologies. No requirement was set for length or depth of ethical discussion, and there was no restriction on the type of article included.

3.2 Data Analysis

All selected articles were reviewed at least twice to identify discussion of ethical implications of PHM. Key terms were identified and combined into themes present across multiple articles. In all, eight themes were recognized based on their usage in the literature. The themes and subsequent analysis were used to identify areas for future research within PHM.

4. Results

A total of 297 articles were returned during the search of databases. After combination with hand-searched papers, 39 met the inclusion criteria of explicitly discussing ethical issues of PHM. On detailed examination of the papers, eight common ethical themes emerged.

4.1 Privacy

Two types of privacy emerged from the articles: personal privacy and data privacy. In general, personal privacy was interpreted to mean the right to be left alone or not monitored by a third party. Several articles identified a gradual loss of personal privacy from increased implementation of PHM technologies, particularly smart home systems (Remmers, 2010, Dorsten et al., 2009, Demiris et al., 2009). The loss of privacy was based on a feeling of constant monitoring among users.

From the collected articles data privacy was interpreted to mean the right to control one's data, including controlling access and use by third parties. Concerns over the usage of data gathered by PHM were more common (Tiwari et al., 2010, Kosta et al., 2010, Agrafioti et al., 2011). In one article an ethical protocol was developed to address concerns by building anonymization features into the data collection process of a wearable health sensor to prevent third party identification of the user (Agrafioti et al., 2011).

Regarding data privacy, it is not clear if the UK's Data Protection Act 1998 governing personal and medical data will apply to all data collected by PHM devices. In particular, it is not clear if data collected by lifestyle monitoring systems which can record "every move, every action, many bodily functions, activities of daily living, whereabouts, [and] comings and goings from the house," will fall under the definition of "personal data" as defined by the Act (Bowes et al., 2011). As a result, the possibility of misuse or undesired access to personal data is raised. This could be a significant ethical issue following widespread implementation of PHM (Bowes et al., 2011). One solution proposed by an American "reality mining" research team facing similar worries of data misuse involves giving patients ownership of most or all of their PHM data (Pentland, 2009).

Personal privacy tended to be seen in the literature as being given up in favor of the perceived benefits of using PHM, which is discussed below. However, in one Swedish example privacy, a sense of being cared for and liberty were improved among elderly users of a PHM device which provided monitoring data to individual caregivers (Essén, 2008).

4.2 Visibility

Visibility or "obtrusiveness" was identified as relevant to the acceptance and long-term use of PHM, although a definition of either term was rarely offered (Robinson et al., 2007, Hensel et al., 2006)). Visibility appears to refer to the degree to which a PHM device is noticeable by the user and other individuals, both at home and in public. In accepting the use of tracking devices for dementia patients, cognitively intact older adults identified ease of use, size and weight as important in accepting a tracking technology (Landau et al., 2010b). As proof of the importance of these criteria, dementia patients discussing the risks and management of wandering believed monitoring devices may place them at greater risk for theft when wandering outside, demonstrating a potential misunderstanding of GPS tracking devices which are designed to be small and unobtrusive (Robinson et al., 2007). This study suggests that patient education on the range of available devices and their use is central to reducing concerns over visibility.

An example of a PHM device achieving low visibility occurred in a Swedish study of adults who reported, following extended use of PHM, that the system faded into the background and was not perceived during daily use. Instead, it was imagined that their caregiver was monitoring them through the device, meaning the caregiver was perceived as “present” in the home on a constant basis (Essén, 2008).

An issue related to visibility is “covert” surveillance. Monitoring devices, particularly smart home technologies, are designed to be inconspicuous to facilitate blending into the home environment. While this may initially promote acceptance of the technology and personal comfort, elderly users who experience increasing cognitive impairment may eventually forget entirely about the monitoring equipment, leading to a form of “covert” monitoring that raises questions of consent (Bowes et al., 2011).

4.3 Medicalization as applied to PHM

Medicalization was rarely used as a term in the collected literature, although several articles described issues that can be interpreted as medicalization of the home environment.

In the context of PHM, medicalization means the devices have the effect of reminding the user or occupants of a medical condition in a non-medical environment. To this end there exists a risk for developers of PHM technologies to view the home environment as a blank canvas for medical monitoring technologies, or “just a machine” (Gentry, 2009). In this case the home could be turned into a medical environment or “de facto intensive care unit,” eliminating the public-private divide between home and “brick and mortar” medical environments (Demiris and Hensel, 2009, Chan et al., 2008, Bowes et al., 2011).

A related issue is that of stigmatization associated with being monitored, which is especially pertinent in community settings for the elderly (Courtney, 2008). Participants reported that using PHM devices could lead to a feeling of frailty based on the need to be monitored, although it was suggested that such a problem could be solved through community wide implementation of identical PHM setups (Courtney, 2008). Attractive as this solution may be, it violates the principle that PHM solutions should be deployed to fit the individualized needs of the user to avoid “monitoring for monitoring’s sake”(Bowes et al., 2011).

4.4 Social Isolation

Concern over increased social isolation was present in several articles based on the possibility that visits from medical personnel may be less necessary if daily monitoring is controlled by a PHM device (Stowe and Harding, 2010, Tiwari et al., 2010, Demiris et al., 2004). In particular, if PHM is viewed as “caring” for an elderly user in the sense that medical personnel will be alerted in case of an emergency, human caregivers may feel less responsibility towards the user which could lead to reduced social interaction. This situation may lead to a lack of personal touch between patients and medical personnel which is problematic considering the health benefits of regular social interaction and physical touch (Chan et al., 2008).

While a concern over increased social isolation was common, one article suggested that social networking features built into PHM devices could enhance a user’s social contact with other members of a patient group (Magnusson et al., 2005), but this depends on these features being built in, and used.

4.5 Autonomy

Although autonomy was mentioned in several articles as an important ethical consideration, it was rarely elaborated as a concept. Within the literature a common notion of autonomy was the right to make decisions for oneself. In these terms a potential problem exists if PHM is deployed on a community level using an opt-out system for participation because it violates this sense of autonomy, as imagined in a scenario involving a “smart pillbox” that automatically reveals dosing information to physicians for the patient’s safety (Kosta et al., 2010).

A related issue is the potential for alteration of behavior of recipients of PHM based on the perceived expectations of the technology. In the case of smart homes, recipients may go so far as to alter their daily routine based on the presence of monitoring, for example by sleeping at certain times or not leaving the house for fear of being viewed as wandering (Tiwari et al., 2010). This alteration of behavior can be interpreted as the monitoring systems exhibiting a passive control over the recipients. Further, users of lifestyle monitoring which feeds back suggestions for improved behavior, such as reality mining systems, could actively be influenced to change their behavior based on these suggestions (Pentland, 2009).

A problematic reliance on PHM may also be viewed as an issue of autonomy, particularly regarding smart home technologies that may carry out such tasks as turning off taps and stoves (Stowe and Harding, 2010, Tiwari et al., 2010, Demiris and Hensel, 2009). Monitors that alert medical personnel in the case of emergency may take the decision to call for help out of the hands of the user which could lead to decreased autonomy and reduced self-care among users (Bowes et al., 2011).

4.6 Balance of Principles

The themes mentioned above highlight several “principles” seen as relevant in the current literature on the ethics of PHM. In line with the Beauchamp and Childress (2009) approach these principles are not absolute, but rather are commonly balanced in the literature both by authors and research participants. In several studies with elderly individuals monitoring technologies identified by the participants as problematic were welcomed by current (Courtney, 2008) and potential recipients on the basis that the technology fulfills an important need that outweighs its downsides in the eye of the user (Ding et al., 2011, Courtney et al., 2008, Demiris et al., 2008a, Demiris et al., 2008b, Melander-Wikman et al., 2007). In the case of residents of a long-term care facility concerns over personal and data privacy were overridden by a perceived need for the monitoring technology (Courtney, 2008). An “inherent duality” appears to exist in the views of participants relating to surveillance technology. This duality centers around the moral conflict between freedom and safety, again implying a moral tradeoff in implementing PHM technologies involving third party access to data (Niemeijer et al., 2011). This balancing act or application of the technology within an individualized context was identified as the determining factor in assessing the morality of PHM applications, implying the technology is inherently value neutral (Welsh et al., 2003), which contrasts with the morally-loaded terminology used in advertising the technology to potential users (Nordgren, 2011).

The importance of remaining at home over moving to a care facility such as a nursing home may begin to explain the balancing act seen in several articles. In one study data privacy, personal autonomy and freedom were all promoted by PHM which allowed users to live at home (Essén, 2008). The ability of third parties (caregivers) to view personal health data was not viewed as a violation of the user’s privacy or capacity to make autonomous decisions,

despite the caregiver being likely to give behavior advice based on the data (Essén, 2008). Rather, the move to a nursing home was viewed as violating the individual's data privacy and freedom to escape monitoring because multiple nursing home caregivers would be perceived to have access to their PHM data. In this sense PHM was seen as promoting rather than violating data privacy (c.f. Fairweather and Rogerson, 2001).

Of particular importance in terms of identifying areas in need of further research were two articles examining the family as a morally relevant stakeholder in the implementation of PHM (Gammon et al., 2009, Landau et al., 2010a). Relational aspects of decisions to monitor the health of a family member were identified through the example of parents valuing the health and safety of a child that may favor freedom and autonomy (Gammon et al., 2009), or caregivers valuing safety over the autonomy and freedom of their family member with dementia (Landau et al., 2010a). This balancing of principles within a relationship may be a worthwhile avenue of research regarding PHM's effect on doctor-patient and family-patient relationships.

Other articles examine the balancing of principles by third parties. In one study involving cognitively intact older adults, participants favored implementing tracking technologies for dementia patients on the basis that patient safety was more important than their autonomy or freedom (Landau et al., 2010b). This view was shared by caregivers of people with dementia when addressing patients under their direct care, but the reverse was true for the patients of others, suggesting the primary concern in opinion formation was the "peace of mind" of the caregivers (Landau et al., 2010a).

4.7 Informed Consent and Development

Several articles identified the need for ethical reflection during development and implementation of PHM technologies, but offered little in the way of ethical discussion (Rigaud et al., 2011, Frisardi and Imbimbo, 2011, Kosta et al., 2010, Gentry, 2009, Demiris and Hensel, 2009). In terms of research and development of PHM, it appears impossible to obtain informed consent from recipients of PHM because full understanding of the implications of using PHM cannot be gained without actually using the technology (Demiris and Hensel, 2009, Stowe and Harding, 2010). Piloting methods such as storytelling and prototyping may present a possible solution to this problem.

4.8 Impact on Healthcare Providers

A small number of studies discussed the impact of PHM on medical personnel. One paper examined the problem of engagement and skills development among care workers when a standardized IT system is used to process and categorize medical data (Gerdes, 2008). Although not explicitly discussing PHM, the conclusions reached in this paper suggest that use of PHM systems that involve extensive categorization of data within a standardized template could lead to stunted skill growth among caregivers. Additionally, if PHM devices attempt to provide both care and social interaction, reduced caregiver visits for elderly users could lead to a reduction in recognition of non-monitored symptoms (Gerdes, 2008). In another study examining caregivers and power relationships it was determined that surveillance in a social care setting (both home and community based) can lead to new power relationships among caregivers and recipients, often changing the activities and interaction during caregiver visits (Vuokko, 2008). Finally, one article examined perceived threats to job security among the medical workforce based on PHM taking care of routine daily tasks, particularly among care workers (Tiwari et al., 2010).

5. Discussion

A limitation of the review was the broad definition of Personal Health Monitoring as a restriction on the database search method. Without a common definition in the literature the search method included as many synonymous terms as possible, meaning an exhaustive list of articles addressing all potential ethical issues (e.g. privacy, confidentiality, freedom) was prohibitively large. The database element of the search therefore had to be limited to articles explicitly addressing ethical issues through use of the “AND ethic*” search modifier. Some articles addressing potential ethical issues that did not appear through the search with “AND ethic*” have been identified through the other methods mentioned. Despite this limitation, the current review identifies articles explicitly addressing ethical issues of PHM and areas in need of further research, which will hopefully contribute to common terminology and responsible implementation of Personal Health Monitoring.

The majority of the reviewed literature addresses ethical issues encountered by elderly users of PHM, especially people with dementia. For studies gathering data directly from elderly users few objections to using PHM were found, although a tradeoff between privacy, autonomy and other values to gain the benefits of PHM was frequently mentioned by potential and current users. This balancing of principles suggests that developers of PHM need to be aware of the “human goods” affected by their devices, and to take all appropriate measures to reduce these effects. Smart home and assistive technologies for the elderly have received the majority of attention in this review based on database results, and prior literature reviews focusing on these technologies in residential and community care settings have turned up a wealth of data (Niemeijer et al., 2010, Zwijsen et al., 2011). Although many articles mention these issues, few discuss them in-depth and ethical consensus is far from reached (Niemeijer et al., 2010, Niemeijer et al., 2011, Zwijsen et al., 2011).

Perhaps even more pressing in terms of areas requiring discussion are the implications of PHM use among younger or non-elderly patients, families and medical personnel: of the 39 articles reviewed, three discuss non-elderly patients, three discuss families, and four examine medical personnel, few of which feature in-depth discussions of ethics. Each of these groups is likely to interact with PHM directly or indirectly (i.e. through a patient), so further research is needed to determine what role these stakeholders play in ethical issues arising from its use.

Regarding non-elderly patients, further research is needed because many emerging PHM systems target healthy individuals (lifestyle and behavior monitoring) or disorders not exclusively affecting the elderly such as diabetes or hypertension (Milenković et al., 2006, Agrafioti et al., 2011, Stergiou and Bliziotis, 2011, Lymberis, 2005, Stowe and Harding, 2010). PHM systems developed for the elderly may also be useful for younger users, such as smart pillboxes or sleep pattern monitors. The assumption cannot be made that younger participants are less likely to experience ethical issues by using PHM, especially feelings of stigma and medicalization for younger individuals lacking experience with having medical devices in the home.

Families frequently play a role in caring for the ill, and may therefore be involved with any medical technologies used by the patient as part of their care. Further research is needed to unpack the effect of PHM use within the context of a family and similar support communities. Possible issues include medicalization of the home environment and interfamilial relationships, reduced contact between family caregivers and the sick, and increased freedom for family caregivers. A “balancing of principles” may lead families to accept PHM devices in their home that inadvertently monitor them and guests, thereby

affecting a tradeoff between personal privacy and freedom of the family and the benefits of PHM.

Inadvertent or covert monitoring may affect all people coming into contact with a PHM user, not just their family or caregivers. Any person entering a PHM environment may be automatically monitored without their consent. This issue may be avoided through filters on monitoring devices which are capable of differentiating between strangers and intended monitoring targets through physiological signs, physical traits, etc., meaning strangers could automatically be ignored. Even if a potential solution exists, it is imperative for developers and users of PHM to be diligent about avoiding inadvertent monitoring of non-consenting individuals. This problem could be magnified through the community-wide implementation suggested as a solution to avoid the stigma and social isolation of using PHM.

With regard to social isolation, one proposed solution is to build social networking capabilities into PHM devices to allow patients with similar issues to socialize remotely. While this may help reduce feelings of social isolation, it can also lead to medicalization with an individual identifying themselves as a “patient” or member of a patient group. Further, the user is giving up some of their privacy by sharing personal data or anecdotes with others, something which may not have been necessary prior to using PHM because they were not experiencing social isolation or reduced caregiver visits. In this sense PHM is passively guiding the actions of the user, raising questions of autonomy. It would appear privacy, autonomy, medicalization and social isolation are intricately linked in some uses of PHM in a problematic way.

Multiple papers involved interviews with cognitively intact adults regarding implementation of tracking devices for individuals with mentally degenerative disorders. These studies showed a preference for patient safety over autonomy and freedom. It must be noted that in light of repeated calls for the increased inclusion of people with dementia in empirical research, any attempts to justify implementing tracking technologies in dementia care based on the opinions of healthy older adults or caregivers is inherently problematic and perhaps in violation of the autonomy of people with dementia (Hellström et al., 2007, Cubit, 2010, Mozley et al., 1999, Nygard, 2006). Individuals in early stages of Alzheimer’s and other degenerative conditions often fear loss of autonomy more than death, so it seems counterintuitive to use autonomy-inhibiting devices to ensure their patient safety (Cohen-Almagor, 1996).

Access to data collected by PHM may be given to medical personnel, yet little has been said how this may affect the relationship with patients or paying medical organizations. Regarding physicians, decontextualization of patient symptoms may occur in clinical encounters. Automation of routine tasks may also be possible freeing up medical personnel for other tasks, such as patient interaction. Continuing in the tradition of analysis of doctor-patient interactions, research is needed regarding the effect of PHM on this relationship.

6. Conclusion

In general, ethical issues relating to development and implementation of PHM technologies were given inadequate attention in the reviewed literature. Although several ethical themes were identified, few were given more than cursory treatment in the literature because the explicit goal of many papers was not ethical analysis. Further research into these areas is both appropriate and necessary (preferably) prior to the widespread implementation of these technologies to ensure they are used in an equitable and beneficial manner. This work

contributes to this need for scholarship by suggesting further ethical issues that may arise in the development, implementation and widespread use of PHM.

Additionally, examples of PHM technologies are reviewed and common features are identified in an attempt to contribute to the development of a common definition of PHM. Although this is not the primary purpose of the paper, it is recognized that a common definition would be beneficial to the field.

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PRIVACY, RISK AND PERSONAL HEALTH MONITORING

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Abstract

Personal health monitoring (PHM) systems capable of gathering pervasive physiological and behavioural data are currently in development to supplement existing medical resources. As a technology designed to operate in the private sphere, PHM can digitise, record and analyse the lives of patients, creating opportunities for data sharing, mining and social categorisation. Medical care and health outcomes may be improved through increasingly granular monitoring and personalised interventions, but these outcomes may come at the cost of user privacy and related ethical implications. As an emerging technology, the opportunity remains to proactively respond to the potential normative risks of a PHM-enabled future. In this paper, a critical overview of the treatment of privacy, risk and PHM in academic literature is offered. The current discourse is defined by a conceptually narrow definition of privacy among developers of PHM systems and security architecture, which suggests that emerging PHM systems may fail to meet the context-specific privacy expectations of users.

Keywords

ethics, privacy, risk, security, trust, personal health monitoring, PHM, pervasive health, wearable health, health surveillance, smart home, literature review

1. Introduction

Personal health monitoring (PHM) systems are being developed to supplement medical care with health monitoring outside traditional care environments such as hospitals. The primary factors spurring the development of PHM are the benefits for patients associated with health monitoring at home (c.f. Neild et al., 2004; Ure et al., 2012), and the need to supplement existing medical resources to address the needs of an aging population (Agree et al., 2005; Remmers, 2010; Sadri, 2011; Stuart et al., 2008). Systems are being developed for a range of demographics, with many targeting the elderly and chronically ill.

PHM refers to any electronic device or system that monitors and records data about a health-related aspect of a person's life outside a hospital setting. To qualify as PHM a device must be capable of transferring data to a third party, and be usable by a layperson outside a traditional medical environment such as a hospital. Examples include smart home systems (Demiris and Hensel, 2009) and physiology-sensing 'smart clothes' (Lymberis, 2005). Emerging PHM applications cover a range of tasks within healthcare and public health monitoring, including prevention, treatment, assistance and rehabilitation, as well as occupational and recreational health monitoring (PHM Ethics Consortium, 2012a). Within these areas PHM applications

have a range of purposes including longitudinal data monitoring, pattern recognition and diagnosis, lifestyle feedback, and anomaly and emergency detection (PHM Ethics Consortium, 2012b).

PHM is designed to operate within the private sphere. Devices can be carried with the user or installed in private environments, such as the home, creating a public window into private life. The lives of users can be digitised, recorded and analysed by third parties, creating opportunities for data sharing, mining and social categorisation (c.f. Lyon, 2003). These basic functions may improve healthcare through increasingly granular monitoring and personalised interventions, yet they simultaneously create an opportunity for violating user expectations of privacy and related risks. As an emerging technology, the opportunity remains to proactively respond to the potential risks of a PHM-enabled future. However, anticipatory action requires understanding the normative potential of PHM (Kastenhofer, 2011) according to developers, regulators, academics and potential users. To this end, a critical assessment of current academic literature discussing privacy, risk and PHM was conducted. Gaps in the discussion and conceptual deficiencies were identified, which revealed areas in need of acknowledgement in the development and governance of PHM.

2. Methods

Peer-reviewed articles, reviews and conference proceedings available in four databases (Scopus, IEEE, MEDLINE, and ISI Web of Knowledge) addressing privacy or risk and PHM were reviewed between May and September 2012. The search was without date restrictions, but limited to English language sources.

2.1 Procedure

Sources were located through systematic searching of the databases as well as hand searching and reference tracking. Multiple search techniques were used to ensure comprehensiveness. Recognising 'personal health monitoring' is an emerging term not yet widely used in the literature (Mittelstadt et al., 2011), synonymous and related search terms were used including 'somatic surveillance', 'wearable body sensors', 'pervasive health', 'assistive technologies', 'ambient intelligence', 'health surveillance', 'ambient assisted living', and 'smart home'. All sources were checked to ensure the technology under discussion matched the working definition of PHM, and that a discussion of privacy issues or risks was included.

2.2 Justification

PHM applications often share technological characteristics with ambient intelligence (AmI) and ubiquitous computing (ubicomp) (Bohn et al., 2005). The search technique was designed to limit the results to health applications. It is recognised that privacy issues and risks of non-medical applications of AmI and ubicomp may be relevant to PHM.¹

¹ For a discussion of ethical aspects of AmI and ubiquitous computing, See: (Bohn et al., 2005; Brey, 2005).

The search method was chosen to identify articles explicitly addressing privacy issues and risks of PHM. The results expanded upon a prior literature review of ethical implications of PHM (Mittelstadt et al., 2011), in which privacy was identified as a major theme. Given the frequency with which privacy appears in discussions of ethics of PHM, it was deemed appropriate to conduct a separate review to develop a fuller understanding of its meaning and usage within discourse on PHM. 'Risk' was also added to the search terminology on the basis of criticisms at ETHICOMP 2011 of the prior review, which suggested normative dimensions of emerging technologies are often discussed in terms of 'risk', and evaluated through 'risk assessments', without any mention of ethics.

2.3 Data Analysis

All articles underwent content analysis to develop a narrative overview of treatments of privacy and risk. Key terms were identified, interpreted and combined into themes present across multiple articles in a process analogous to grounded theory (c.f. Strauss and Corbin, 1994). Words and passages were highlighted that appeared to refer to privacy, risk, or normative claims. Highlighted segments were coded. Similar codes were assigned to themes. The frequency with which codes appeared was used as a starting point for discussion of results.

3. Results

A total of 527 articles were identified for review, 81 of which met the inclusion criteria of explicitly discussing aspects of privacy or risk and PHM. Of the reviewed literature, 33 sources discussed designing a PHM system or underlying security or privacy architecture, 20 were empirical studies into user, family or professional attitudes towards PHM, 12 reviewed literature about privacy, risk or security aspects, nine were theoretical analyses or conceptual discussions, five analysed normative dimensions of future scenarios of PHM usage and two were risk assessments. The following sections present a narrative overview of the literature, divided into conceptual themes which emerged. Two general types of privacy emerged: information privacy and personal privacy.

Before proceeding with the overview, definitions are required for terms used in presenting the results. The creators or subjects of data (e.g. who the data is 'about') are denoted as 'users'. This title highlights the interaction between persons and PHM systems, which creates the data affecting privacy. Persons or organisations that handle the data once created are referred to as 'data custodians'. Other stakeholders include the rest of the parties who interact with or possess a claim to the data. For simplicity they are referred to as 'stakeholders'. A 'misuse' of data is any use (e.g. searching, analysis, comparison) to which the user has not consented.

3.1 Information Privacy

A majority of the reviewed literature focused on aspects of controlling and disseminating data about oneself. Information privacy was interpreted as the right to control data about oneself and limit third-party access (c.f. Chan et al., 2009; Demiris, 2009; Jea et al., 2008; Mitseva et al., 2008; Mittelstadt et al., 2011; Tentori et al., 2006; Tiwari et al., 2010; Van De Garde-Perik et al., 2006; van Hoof et al., 2007). At

its narrowest, information privacy was equated with hiding personally identifiable information from unauthorised parties (Ahamed et al., 2007b; Garcia-Morchon et al., 2011), and was seen as quantifiable (Srinivasan et al., 2008). Concerns over data control were common among participants in empirical studies (Coughlin et al., 2007; Courtney, 2008; Little and Briggs, 2009; Melenhorst et al., 2004; Wilkowska et al., 2010). Unauthorised access or identification of the user may be prevented through anonymisation at data collection (c.f. Agrafioti et al., 2011), with access policies allowing chosen actors access to identifiable data (Bagüés et al., 2007b; Garcia-Morchon et al., 2011; Subramaniam et al., 2010) for acceptable purposes (Beaudin et al., 2006; Chakraborty et al., 2011; Massacci et al., 2009). Transparency of relationships between data collected and purposes of collection is central to protecting privacy of users (Giannotti and Saygin, 2010), who make decisions regarding acceptable uses.

Information privacy empowers users to control the information revealed to others about themselves, limiting opportunities for unwanted disturbances and exploitation, caused by an information imbalance. Information enables regulation, behavioural control and social sorting by those with greater access (Kosta et al., 2010), so controlling information flow enhances dignity, autonomy and privacy. Thus, information privacy acts as a check on the power of organisations and data custodians (Friedewald et al., 2007; Moncrieff et al., 2009). Risks associated with uses of personal data beyond those found acceptable (or consented to) by users require “strict guidelines of confidentiality” to prevent unwanted personalised marketing and personalised insurance premiums (Kosta et al., 2010; Percival and Hanson, 2006), or exclusion or discrimination against (non)users wishing to limit access to their personal data (Brey, 2005). To limit possibilities of data misuse and come closer to an ideal of informed consent, information about temporal limitations and purposes for data use need to be available to users before data gathering (Kosta et al., 2010).

Despite empowerment attached to information privacy, absolute control over personal data may not be a necessity for PHM to be accepted by users. Empirical studies into attitudes towards PHM revealed a preference to forego information privacy in emergency situations (Rashid et al., 2007; Steele et al., 2009), which highlights the need to find a balance between the desire to control data and enjoy the benefits of services which require that data. A similar balance is expressed in preferences towards PHM for data gathering over human intrusion into the home (c.f. Essén, 2008). User-end policies have been proposed as a solution which allows users to pre-define a customized level of privacy meeting their expectations (Friedewald et al., 2007; Garcia-Morchon et al., 2011; Massacci et al., 2009).² Privacy tools such as these are said to enable users to freely move between and interact with a range of PHM systems without negotiating individual privacy agreements, while respecting the necessity of informed consent (c.f. Bagüés et al., 2007b).

Security

² User ownership of personal data has also been suggested as a solution to data mining risks presented by PHM (Pentland, 2009); this solution would, however, present a significant barrier to the realisation of legitimate commercial and research interests, and would require sophisticated legislation detailing appropriate third party uses of personal data without the explicit consent of the data owners.

Although not explicitly searched for, security emerged as a theme in information privacy literature. Privacy and security were frequently conceptually interchangeable (c.f. Ahamed et al., 2007a; Armac et al., 2009; Busnel and Giroux, 2010; Chan et al., 2008; Dhukaram et al., 2011; Elkhodr et al., 2011; Garcia-Morchon et al., 2009; Mana et al., 2011; Stuart et al., 2008; Wang et al., 2008); ensuring system security through appropriate frameworks and encryption algorithms was taken to guarantee user privacy. The concepts can be differentiated by their ends: security is concerned with guaranteeing the *quality* of the data collected by and passing through a system in terms of “confidentiality, integrity and availability” (Giannotti and Saygin, 2010), enabling users to protect *privacy* by controlling dissemination of personal data. Under this distinction, security mechanisms may alert a user to unrecognised flows of information between systems and stakeholders (Moncrieff et al., 2009), which could be limited to respect the user’s information privacy.

Security risks were defined in terms of interception, modification and falsification of sensor data (Acharya and Kumar, 2010; Lim et al., 2010), and authentication scheme (Giannetsos et al., 2011; Massacci et al., 2009; Subramaniam et al., 2010).³ Security frameworks including key management schemes, encryption algorithms and (actor-based) authentication mechanisms were seen as protecting the confidentiality, integrity and flow of information passing through PHM systems (Acharya, 2010; Chan et al., 2009; Fragopoulos et al., 2010; Giannotti and Saygin, 2010).⁴ In these terms, security features protect a user’s ability to control and trust his data—the conceptual confusion seen in the reviewed literature is therefore unsurprising.

Trust

Trust, understood as a security concept, emerged in the reviewed literature as necessary component for PHM systems to be seen as ‘privacy enhancing’ (c.f. Bagüés et al., 2010; Chakraborty et al., 2011; Coughlin et al., 2009; Dhukaram et al., 2011; Rashid et al., 2007; Wang et al., 2008; Yuan et al., 2007), when privacy is interpreted as control over personal data. Trust is defined in the context of information privacy as an interaction between a system which collects and processes data, users which provide the data, and stakeholders who access it. A lack of trust in a system has been linked to reluctance among potential users to use systems (Brey, 2005; McLean, 2011). Users ‘place trust’ in systems and stakeholders to handle their data responsibly, which facilitates and secures data sharing (Bagüés et al., 2010; Kosta et al., 2010; Little and Briggs, 2009). Trust can be understood as a sum of the credibility, motivation, transparency and responsibility of a system. Credibility is linked to ‘loyalty’ or ‘reputation’ (Little and Briggs, 2009; Rashid et al., 2007); a stakeholder must be seen as responsible or credible enough to handle sensitive personal data. Motivation refers to the intentions of stakeholders, or how they intend to use the data of users. Monitoring of parameters or putting data to uses beyond those explicitly agreed upon by users was taken to undermine trust. These motivations, and intended uses of data, should be transparent to users, as should the sum of data collected and held about them. To achieve trust, systems must allow users to review and control their data.

³ An extensive review of technical security risks is provided by Armac et al (2009).

⁴ Confidentiality refers to limiting access to data to stakeholders with authorisation (Giannetsos et al., 2011; Giannotti and Saygin, 2010).

3.2 Personal Privacy

Personal privacy describes aspects of privacy not directly related to control of data. Personal privacy was interpreted to mean the right to be left alone or not monitored by a third party (c.f. Demiris and Hensel, 2009; Dorsten et al., 2009; Mittelstadt et al., 2011; Pallapa et al., 2007; Wilkowska et al., 2010), which affects feelings of intimacy and control over 'private space' (Gaul and Ziefle, 2009; Ziefle et al., 2011).⁵ Personal privacy can also be understood as a freedom, to "escape being observed or accessed when desired" (Essén, 2008), implying a social duty to respect the desire for isolation of others. The introduction of PHM may cause a gradual loss of personal privacy (Steele et al., 2009), particularly among smart home systems (Coughlin et al., 2007; Demiris, 2009; Dorsten et al., 2009). Monitoring technologies can create a psychological disturbance, sometimes called obtrusiveness (c.f. Hensel et al., 2006; Nefti et al., 2010), expressed in a feeling of 'being watched'; certain technologies, particularly cameras (Caine et al., 2006; Demiris et al., 2004; Leone et al., 2011; Stowe and Harding, 2010; Tiwari et al., 2010; Zwijsen et al., 2011), produce greater perceived violations of personal privacy in this regard.

Personal privacy is a multifaceted concept, defined by interactions between social individuals, ICT and the natural world. As seen in the reviewed literature, personal privacy includes:

- **Physical Privacy** – Physical accessibility of a person to others, defined by physical borders, such as doors and walls (Bowes et al., 2011; Brey, 2005; Essén, 2008; Little and Briggs, 2009). This can also be interpreted as a right to possess and protect personal space (Kosta et al., 2010), such as a home.
- **Social Privacy** – Control over social interaction through geographical distance, group membership and location. It is connected to physical privacy (Bagüés et al., 2007a; Coughlin et al., 2007; Little and Briggs, 2009), and can contribute to social isolation.
- **Decisional Privacy** – Absence of undesired interference from others in making decisions (Bowes et al., 2011; Essén, 2008). Decisional privacy enables the expression of autonomy.

Physical and social privacy are placed at risk by PHM capacities to transmit data to third parties (Brey, 2005; Friedewald et al., 2007), or move personal data past privacy protecting natural, social, spatial, temporal, ephemeral and transitory borders (c.f. Marx, 2001). PHM increases the interconnectness of users and stakeholders through data sharing which blurs the boundaries between 'public' and 'private' spaces and data.

Decisional privacy is placed at risk by monitoring when interpreted by users as a form of electronic surveillance; awareness of monitoring can affect behaviour (Essén, 2008), especially risk taking among seniors (Percival and Hanson, 2006; Remmers, 2010) which can represent a desire to retain independence at home, despite safety risks. Monitoring may also lead to 'labelling' of users as 'health impaired' or 'at-risk'

⁵ The distinction between personal and information privacy was not always upheld in the reviewed literature, with control over dissemination of personal information occasionally understood as a form of personal privacy (c.f. Bagüés et al., 2010).

(McLean, 2011; Percival and Hanson, 2006; Rigby, 2007), further limiting behavioural freedom (Kosta et al., 2010). Alternatively, the user's home may be increasingly freed from external interference by reducing the need for carer visits. Whether this outcome is desirable, particularly among the mentally impaired and physically frail, remains a question of appropriate balances between safety, autonomy and self-determination (c.f. Remmers, 2010). The need for 'self-care' among users can also be reduced by violations of decisional privacy, if for example PHM takes the decision to call for help out of the hands of the user (Bowes et al., 2011). In this case, user privacy is violated through automatic sharing of personal data, which causes intrusion of a third party into a user's private space.

3.3 Information and Personal Privacy Overlap

The conceptual distinction between information and personal privacy is not always clear. By controlling the dissemination of personal information, a person may be spared future physical, social and decisional disturbance from third parties, such as friends, family and service providers (c.f. Friedewald et al., 2007). Many privacy risks described in the literature cannot clearly be separated into information or personal privacy. For example, the visibility of a PHM system to others can cause the user to experience stigma (McLean, 2011), because the device's visibility transmits information to others without the user's consent, while also influencing behavioural and decisional freedom in public.

Technological 'Need' and Privacy

Monitoring is understood to inherently raise questions of privacy, but potential violations can be justified on the basis of 'need' for the technology, derived perhaps from safety concerns related to health (Steele et al., 2009; Zwijsen et al., 2011), or to delay a move to residential care (Essén, 2008; McLean, 2011; Remmers, 2010; Townsend et al., 2011). This type of 'tradeoff' demonstrates the potential for PHM to simultaneously violate and enhance privacy. A tradeoff was often presented between personal privacy and safety, particularly among the mentally impaired (Landau et al., 2010; Ojasalo et al., 2010; Stowe and Harding, 2010), as well as frail elderly (Courtney, 2008; Courtney et al., 2008; Melenhorst et al., 2004; Steele et al., 2009) and chronically ill persons (Neild et al., 2004; Salih et al., 2011). In this context, it was suggested that personal privacy could be simultaneously enhanced by reducing need for carer or family visits (Essén, 2008; Ojasalo et al., 2010), but reduced by the presence of a monitoring device invading the user's 'private' sphere. In community care situations, personal privacy is typically desired with regard to other patients, rather than carers. However, in the home the opposite is true (Essén, 2008); freedom from professional carers enabled by PHM can increase the tradeoffs, in terms of privacy, autonomy and other ethical values, that are seen as acceptable. These tradeoffs may be seen as a necessary part of aging, with increasing susceptibility to health problems (Steele et al., 2009), though this view should not be applied generally to associate 'aging' with reduced expectations of privacy, or to justify increased privacy violating interventions.

3.4 The Absence of Risk

"Privacy" and "risk" were treated as independent concepts in the search terminology. Initial expectations were that 'risk' would prove to be a robust concept, revealing

ethical and social dimensions of PHM beyond those identified in the previous literature review (Mittelstadt et al., 2011), given that risk is often used as a generic term to refer to the normative dimensions of (emerging) technological artefacts (c.f. Busnel and Giroux, 2010; Hilty et al., 2004; Kastenhofer, 2011; Morris, 2000). The discussion of risk in the reviewed literature is limited almost exclusively to privacy and security implications (Lim et al., 2010; Nefti et al., 2010; Pentland, 2009; Sadri, 2011) or risk taking behaviours of seniors (Percival and Hanson, 2006; Remmers, 2010). Risk was rarely conceptualised as a future-oriented concept, as seen in risk assessments of future scenarios (c.f. Friedewald et al., 2007; Kastenhofer, 2011). The inclusion of 'risk' as an independent concept did not contribute content beyond themes addressed. The exception was a risk assessment identifying normative aspects of pervasive computing including environmental and human effects of non-ionizing radiation, stress imposed on users, restriction of consumers' and patients' freedom of choice, threats to ecological sustainability, and dissipation of responsibility in computer-controlled environments (Hilty et al., 2004).

4. Discussion

PHM privacy discourse, represented in the reviewed literature, overwhelmingly addresses protection of information privacy through security measures, while dedicating far less attention to the importance of personal privacy and context-specific norms (c.f. Nissenbaum, 2004). This finding is especially true of sources discussing the development of PHM systems and underlying security architecture, of which only three mention aspects of personal privacy (Bagüés et al., 2007a; Neild et al., 2004; Pallapa et al., 2007). While other types of sources addressed personal privacy, few references were found to background normative theory or theories of privacy. In many sources discussion of privacy, risk and related concepts was very brief, limited to few sentences or paragraphs, although longer discussions were not rare (c.f. (Brey, 2005; Friedewald et al., 2007; Gaul and Ziefle, 2009; Little and Briggs, 2009; Remmers, 2010; Ziefle et al., 2011). Privacy was often seen as a hurdle to be overcome to make systems acceptable to users by protecting their right to control their data (c.f. Zwijzen et al., 2011), rather than as a broad normative concept with context and user-specific norms.

These results reveal two significant gaps in the literature: (1) system and security developers fail to explain their understanding of privacy and related concepts (e.g. security, trust, confidentiality) from a theoretically informed position; and (2) aspects of personal privacy which cannot be addressed through system and security development receive comparatively little attention. This suggests a disconnect exists between theoretical and applied disciplines, in which theoretical development of privacy as a normative concept fails to inform development of PHM systems and underlying security architecture.

Explicit definitions and discussions acknowledging the conceptual complexity of privacy were scarce in security-oriented literature⁶, suggesting that systems are being designed and secured under the impression that privacy protections function generically across a variety of contexts. This fails to acknowledge the context-sensitivity of (expectations of) privacy (Nissenbaum, 2004), and risks presenting

⁶ Of the 81 sources reviewed, only 27 explicitly defined privacy or risk.

systems as ‘privacy-enhancing’ (c.f. Subramaniam et al., 2010) which are merely technically secure: “The idea is tempting: once we solve security, that is, once we are able to achieve authenticity and trusted communications, privacy will be a by-product that follows inevitably from a secure environment...The important aspect to realize is that security might not be the panacea it appears to be, and it might not need to be that panacea either” (Langheinrich, 2001). When privacy is seen as a complex, multi-faceted normative concept inspiring a rich history of normative theory, the simplistic, ‘one-size-fits-all’ approach to security in PHM appears insufficient.

The narrow conception of privacy, by which privacy is reduced merely to control of data, risks simplifying future discourse, design and governance of PHM by ignoring personal, context-sensitive aspects of privacy. Current discourse risks devaluing experiences of users falling outside of the narrow scope of privacy defined in terms of data. Furthermore, it is problematic to claim that a PHM system or security mechanism is ‘privacy-enhancing’ (c.f. Garcia-Morchon et al., 2009; Pallapa et al., 2007) without demonstrating awareness of the conceptual complexity of privacy, and underlying theories of privacy. The need to expand the scope of the discourse has been recognised (Caine, 2009), but remains largely unrealised as evidenced by the relatively few sources which provide in-depth discussions of aspects of privacy beyond security or data control.

This feature of current discourse may be a result of application developers lacking expertise in security (Busnel and Giroux, 2010), privacy and ethical theory, while simultaneously failing to acknowledge research in these areas.⁷ This is not to suggest that developers need to engage in theorising, especially in reporting on new systems, security measures and frameworks in conference proceedings and academic journals. Rather, what was lacking from ‘applied’ discussions in the reviewed literature was *awareness* of the complexity of privacy, security and risk, and the ethical and social scientific works which demonstrate the difficulties associated with ‘universal’, acontextual conceptions of privacy (c.f. Nissenbaum, 2004). The literature suggests developers understand privacy one-dimensionally: privacy is control over data about oneself, and is guaranteed through security mechanisms. If this simplified conception becomes embedded in system design, users face a future of ‘privacy enhancing’ health monitoring systems which may fail to meet their privacy expectations in practice. To mitigate this risk, developers and regulators need to better explicate their conception of privacy and its theoretical foundations, and identify how it is translated into system design. Furthermore, achieving a context-sensitive understanding of privacy requires understanding attitudes and expectations of stakeholders (McLean, 2011), as well as practice-internal norms (MacIntyre, 1984; Nissenbaum, 2004) of information dissemination and fair usage unique to the context(s) in which a particular PHM application will be used. Empirical research (c.f. Gaul and Ziefle, 2009; Little and Briggs, 2009; Ziefle et al., 2011) and participatory design methods (c.f. Genus and Coles, 2005; Joss and Bellucci, 2002) which address these needs are readily available, and need to be explicitly utilised by developers.

⁷ The limitation of privacy to data control, dissemination and security aspects by developers matches Westin’s influential conception of privacy as the right of individuals “to control, edit, manage, and delete information about them[selves] and decide when, how, and to what extent information is communicated to others” (1970).

By failing to address personal privacy in the design of PHM systems and security, the design discourse is ignoring intrusions by third parties into the 'private' lives of users unrelated to data dissemination (see: Section 3.2). Data sharing is at the heart of such disturbances, yet describing the normative character of these violations in purely informational terms misses the disturbing aspect of the intrusion—it is the fact that data is being collected or shared, rather than the content of the data, which is seen as problematic. In other words, PHM systems disturb users through the introduction of third parties into their private spaces and decisions. This aspect of PHM, which can be described in terms of psychological obtrusiveness (c.f. Hensel et al., 2006), has not yet received the attention it deserves in the literature, perhaps because its solution does not lie (only) in 'designing for security'.

The importance of correcting this deficiency in the discourse also lies in the great potential for PHM to violate privacy expectations of users in collecting and handling extremely sensitive personal data. PHM gathers data about health, often within the confines of the home (Rashid et al., 2007). Systems are being implemented to monitor these sensitive domains, yet it is doubtful that users understand the systems' potential, in terms of violations of privacy and data mining (Beaudin et al., 2006). Data can be collected and presented in potentially distressing or revealing formats, connections can be identified between seemingly unrelated pieces of information, and a range of unforeseeable secondary uses of increasingly rich longitudinal data sets are possible. Users may assume that developers and data custodians have 'protected them' from unanticipated consequences through appropriate privacy policies (Rashid et al., 2007), creating a space in which privacy violations can occur beyond the awareness of the user.⁸

5. Conclusion

The results of this review reveal that the current discourse of privacy, risk and PHM is dominated by concerns related to controlling the dissemination of personal information. While in-depth discussions of non-information aspects of privacy do exist, they have failed to impact upon the discourse surrounding system development and security, which generally operate upon a narrow definition of privacy as 'information privacy'. It follows that systems designed to meet myopic interpretations of privacy may fail to meet the privacy expectations of future users of PHM. To improve the discourse, background normative theories of privacy, autonomy and self-determination (c.f. Hoven, 2008; Nissenbaum, 2004; Rossler, 2004), among others, need to be applied to improve the development and governance of PHM.

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⁸ This situation raises a philosophical question regarding whether a user must 'care about' their privacy for violations of privacy to occur. Unfortunately, addressing this complex topic goes beyond the scope of this review.

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PHM-Ethics and ETICA: Complementary Approaches to Ethical Assessment

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Abstract. The chapter undertakes a comparison of different approaches to the ethical assessment of novel technologies by looking at two recent research projects. ETICA was a FP7 sister project to PHM-Ethics, responsible for identification and ethical evaluation of information and communication technologies emerging in the next 10-15 years. The aims, methods, outcomes and recommendations of ETICA are compared to those of PHM-Ethics, with identification of linkages and similar findings. A relationship is identified between the two projects, in which the assessment methodologies developed in the projects are shown to operate at separate, but complementary levels. ETICA sought to reform EU ethics governance for emerging ICTs. The outcomes of PHM-Ethics are analyzed within the policy recommendations of ETICA, which demonstrate how the PHM-Ethics toolbox can contribute to ethics governance reform and context-sensitive ethical assessment of the sort called for by ETICA.

Keywords. ETICA, PHM-Ethics, ethics, anticipatory, emerging technology, ICT, personal health monitoring, ambient intelligence, governance

Introduction

As novel technologies are developed and implemented in various contexts of use, normative issues accrue which must be addressed at local, national and international levels. Within the EU, this need for 'ethics governance' is met through a variety of approaches including research, policy, and ethics review committees. The EU approach to governance has been found lacking in its ability to respond to the challenges presented by emerging information and communication technologies (ICT), both in terms of proactive identification and resolution of normative issues, and in the development of context-sensitive solutions and understanding of norms and moral values. The 7th Framework Programme (FP7), sponsored by the European Commission, placed calls for the development of approaches for ethical, social and legal assessment of emerging technologies to address the limitations of current governance.

PHM-Ethics and ETICA were among the research projects that responded to these calls. ETICA was a sister research project to PHM-Ethics, which focused on the ethical implications of a broad set of emerging ICTs. Through a shared orientation towards policy and development, the two projects provided concrete recommendations and practical tools for ethics governance based upon interdisciplinary theoretical and empirical perspectives and methodologies. This chapter focuses on the similarities

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between these complementary projects, in terms of overlapping aims, methods, outcomes and recommendations.

Responsible innovation requires the integration of ethical, social and legal perspectives into ICT research, development and regulation. Despite their disparate technological foci, the sister projects provide complementary analyses and assessment tools for the improvement of innovation and ethics governance within the EU. Consideration of their outcomes and recommendations together will therefore strengthen practical activities aimed at proactively identifying and resolving ethical implications of Personal Health Monitoring (PHM) in particular, and emerging ICTs in general.

The structure of the chapter reflects the exploration of linkages between the two FP7 research projects, achieved through comparison of aims, methods, ethical issues and outcomes. The chapter opens with a brief summary of each project, followed by a thematic summary of their aims and scope in Section 2. Interdisciplinary methods of identification and evaluation of ethical, social and legal issues are then reviewed in Section 3, followed by a comparison of the ethical issues of Ambient Intelligence (Aml) in ETICA, and PHM in PHM-Ethics, respectively. Section 5 compares outcomes and the assessment methodologies built and validated in each project, concluding that as part of ongoing dissemination activities the two methodologies should be united to improve ethics governance and responsible research and innovation in the EU. The primary contribution of both projects was the creation of compatible methodologies for the ethical assessment of emerging ICTs, representing a unified European perspective.

1. Project Summaries

Before detailed comparisons can be made between the projects, it is helpful to summarize their aims, scope, methods and outcomes.

1.1. ETICA²

ETICA (Ethical Issues of Emerging ICT Applications) was a European Commission funded research project under the 7th Framework Programme (GA 230318) which ran from April 2009 to May 2011. Its objective was to identify and evaluate emerging ICTs, potential applications, and their ethical implications. These activities, supported by critical evaluation of existing ethics governance in the EU, led to policy recommendations intended to facilitate proactive and acceptable evaluation of the ethics of emerging ICTs [1]. The project included partners from universities throughout Europe to ensure a broad European perspective.³

Review of ICT ethics literature led to the identification of eleven emerging technologies with predicted ethical relevance: Affective Computing, Ambient Intelligence, Artificial Intelligence, Bioelectronics, Cloud Computing, Future Internet,

² Further information on ETICA, including project deliverables and reports can be accessed via the ETICA website at: <http://ethics.ccsr.cse.dmu.ac.uk/etica>.

³ Project partners: De Montfort University (UK), VTT Technical Research Centre (Finland), Delft University of Technology (Netherlands), Forschungszentrum Karlsruhe (Germany), University of Namur (Belgium), Steinbeis University Berlin (Germany), Eötvös Károly Public Policy Institute (Hungary), University of Lodz (Poland).

Human/Machine Symbiosis, Neuroelectronics, Quantum Computing, Robotics and Virtual/Augmented Reality. Technologies were defined as “high-level socio-technical systems that have the potential to change the way humans interact with the world” [1, p.4]. Emergence hinged upon current research and development, which indicates technologies that will be socially and economically relevant in the next 10-15 years.⁴ The identified emerging technologies are expected to overlap in future ICT developments, and are believed to exist in an enabling hierarchical relationship [1, p.15], in which ethical implications are shared across multiple technologies. A methodology for identification and evaluation of the technologies, ethical, legal and social issues, and limitations of current governance was described and validated within the project. Once identified, ethical issues of the eleven technologies were ranked according to severity judged from an interdisciplinary perspective.

Recommendations were aimed towards policy-makers and industry which sought to improve current ethics governance approaches. While policy-makers were recommended to establish an environment in which participatory ethics governance is required and supported, industry, researchers and civil society organizations (CSOs) were encouraged to use the tools provided by policy-makers to undertake ethical assessment before implementation of emerging ICTs.

1.2. PHM-Ethics⁵

The main aim of the collaborative PHM-Ethics research project was to “conduct scientific interdisciplinary research to analyze the dependencies between ethics, law and psychosocial sciences in personalized health monitoring in relation to the major types and steps of this very dynamic part of IT-development from a European perspective” [2, p.8]. PHM was defined as “all technical systems collecting, processing, and storing data linked to a person. It allows monitoring parameters of that person and can lead to health-related information of that person” [3, p.6]. An integrated European approach to the combined regulation of ethical, philosophical, legal and psychosocial constraints was developed [2]. PHM-Ethics was funded under the European Commission’s 7th Framework Programme (GA 230602).

Strong emphasis was placed on the creation of a reflexive, open-ended PHM-Ethics ‘toolbox’ for ethical, legal and psycho-social assessment of emerging PHM applications in future contexts. An assessment methodology was developed to meet this goal consisting of five components:

1. **Dependencies Map.** A multi-layered, complex network of relationships that illustrates dependencies and relationships between parties involved in PHM.
2. **Taxonomy.** A classification system which categorizes PHM technologies and applications representing the state of the art in PHM. It generates groups with similar characteristics and allows users to make distinctions between similar technologies.
3. **Psychosocial Assessment Module.** An integrated module for psycho-social health technology assessment. It consists of a map highlighting selective

⁴ The 10-15 year period was chosen to reflect the technology development life cycle. Technologies currently in development are expected to be implemented and impact on humans and society in that timeframe.

⁵ Further information, deliverables and dissemination activities can be found on the project’s web-site: <http://ethics.p-h-m.org/>. First paragraph taken from the PHM-Ethics Final Report.

psychosocial issues of relevance when applied to a PHM application. It covers various domains of technology perception and psychosocial outcome criteria.

4. **Ethical Assessment Module.** A module which allows evaluating existing and upcoming PHM technologies from an ethical point of view. Ethical values and principles are put into perspective with Personalized Health Monitoring. It provides questions in the fields of privacy, autonomy, freedom of choice, justice, and further content relevant in PHM ethical assessment.
5. **Legal Framework.** A comprehensive legal report that describes the legislation at the European level, regarding telemedicine and/or health monitoring. It takes into account the consequences of recent decisions by the European Court of Justice important for PHM, dealing with privacy and reimbursement of monitoring systems. Limitations and gaps in current regulation and governance schemes are identified, along with differences in ethical constraints between EU directives and national legislation [2, p.8-9].

Each methodological component can be viewed as an assessment tool to be applied to future PHM applications and contexts. The tools are complementary in the sense that results from one can be used to inform application of the others. For example, the created methodology allows for assessment at multiple levels of the taxonomy, guided by the interrelationships identified in the dependencies map. They can also be considered provisional, as it is the intention of the project consortium to update the taxonomy and dependencies map in light of future PHM developments. While created for PHM, the project consortium has started to test the methodology with other emerging ICTs⁶ in accordance with the goals of FP7 [2].

Recognizing the importance of context in understanding the future ethical implications of PHM, an ethical assessment questionnaire was created which explores ethical implications according to stakeholders. The ethical assessment methodology created in the project, although general enough to be applied to a diverse range of future PHM applications, nonetheless provides a tool for individualized context-sensitive assessment.

If widespread adoption of this methodology by EU policy-makers and industry occurs, a reduction in the time between development, ethical assessment and implementation is expected. Facilitation of a proactive approach to ethics governance, in which context-sensitive participatory assessment occurs simultaneously with development, is therefore the overall goal of PHM-Ethics. The developed tools assist in both identifying and managing emerging ethical issues of PHM through engagement of stakeholders in these processes. Furthermore, an evidence base is created for evidence-based policy-making through assessment with the PHM-Ethics toolbox.

2. Project Aims

The 7th Framework Programme emphasizes the need for ethically and socially aware innovation in the EU. PHM-Ethics and ETICA both contributed to this need through the development of a European perspective on the ethics of PHM and emerging ICT, respectively. The necessity of a unified European perspective is based upon recognition of the central role played by ICT in society, business and research.

⁶ For example, the dependencies map technique has been used in considering e-commerce in Saudi Arabia in PhD research by Fahad Aleid at De Montfort University.

Acknowledging that all ICT has potential ethical and social implications, incorporation of a diversity of stakeholder perspectives in ethics governance becomes paramount in societies guided by democratic ideals. The establishment of an EU perspective in these projects allows for recognition of the shared values between member states, and contributes to the establishment of widely acceptable standards for responsible research and innovation.

2.1. Contributions to European Discourse

The importance of proactively identifying and dealing with ethical problems arising from ICT innovations was emphasized in both projects. Proactive ethical assessment of emerging ICT is required to prevent foreseeable ethical problems from occurring. While the predictions made in the projects may never come to pass, the position of uncertain proactivity is preferable to merely reacting to ethical problems as they occur [1]. Researchers, policy-makers and civil society tend to undertake actions meant to shape the future in desirable directions without absolute certainty over its course [4,5]; proactive ethical assessment should be seen in this light.

The aims of ETICA and PHM-Ethics need to be viewed with the desirability of proactive ethics in mind. Future-oriented research is seen as inherently uncertain; foresight and scientific predictions are not analogous. The contributions of these projects are done a disservice when conceptualized as merely predictions, to be evaluated on the basis of whether or not they come true. Rather, foresight research contributes to discourse on the future of European societies as shaped by emerging ICT innovations. Each project provides an overview of possible ethical issues emerging from ICT currently in development or on the horizon. When considered alongside analysis of the limitations of current regulation and governance frameworks, the projects provided a well-grounded basis for future discourse and ethical assessment within specific future contexts, as created by the interaction between policy-makers, civil society and emerging ICTs.

2.2. Technological Scope

The scope of ETICA was much broader than that of PHM-Ethics. Both projects focused on technologies, as opposed to artefacts or applications. A distinction was made between these three in ETICA, seen as a spectrum proceeding from general to specific [1]. To use 'smart homes' as an example: PHM is a technology, sensors around the home are artefacts, and fall detection combining data from various sensors is an application.

ETICA focused on 'high-level' technologies [1, p.4], and based ethical analysis on general defining features of each technology as opposed to specific applications. However, general descriptions of emerging applications were created to assist with ethical analysis. Although PHM was not identified as such in ETICA, many (but not all) PHM applications would fit under its definition of Ambient Intelligence.

PHM-Ethics, although very broad in its definition of PHM, was comparatively focused by exploring a specific area of use (health and medicine). Even so, the technical possibilities and ethical implications of the many sub-fields and applications of PHM preclude an insightful evaluation at the artefact or application level. General procedural codes were therefore developed for application to PHM as a high-level

technology. This focus was appropriate considering the early stage of development and implementation at which PHM currently exists; broad EU regulatory frameworks are still feasible.

2.3. Analytical Disciplines

The analytical perspectives taken varied in the projects, although similarities were found. Both ETICA and PHM-Ethics analyzed emerging technologies from ethical and (EU) legal perspectives, with awareness of current challenges in these areas based on research into existing and analogous technologies. PHM-Ethics developed a psycho-social analytical module, while ETICA included perspectives on gender. Technology Assessment informed a critical analysis of current governance schemes in ETICA, and formed the basis for the ethical assessment tool (EAT) developed in PHM-Ethics [6]. The influence of the interdisciplinary approach was seen clearly in PHM-Ethics in the Dependencies Map, which revealed interrelationships between ethics, law, medical informatics, psycho-social and medical sciences [2].

2.4. Procedural and Substantive Aims

In contrast to prior procedural governance approaches[7], neither project sought to provide a comprehensive list of ethical issues and solutions for emerging ICTs or PHM, respectively. Rather, each sought to provide early indication of potential ethical issues for policy-makers and civil society, with recommendations for further discourse between stakeholders to seek solutions. Beyond providing a basis for discussion of the issues, the projects developed methodologies for the incorporation of ethical, social and legal methodologies into innovation and governance.

It is useful to distinguish between the procedural and substantive aims of the projects. Procedural aims relate to the development of methodologies and assessment tools for future ethical assessment, while substantive aims consist of the identification and evaluation of ethical, social and legal issues of the respective technologies. While links between the substantive outcomes of each project are highlighted below, greater importance is placed on procedural outcomes due to the transience of substantive results. Ethical issues based upon defining features of the technologies were highlighted in each project, yet these issues will change according to future developments and contexts. A list of future issues can therefore never be considered comprehensive or complete. While the substantive outcomes of each project are important for sketching our current understanding and concerns with the future, and for guiding discussion of these issues, the generic methodologies developed in each project assume more importance for their ability to shape future discourse. The procedural outcomes of each project are “future-proof” in the sense that they have been designed for application to both predicted and unforeseeable future technologies, applications and contexts.

The relative importance of procedural versus substantive outcomes can best be seen in the recommendations from each project, which emphasize the inclusion of ethical perspectives in development and regulation. The resulting discourse can be guided by the substantive contributions of each project, facilitated in ETICA by the establishment of an ICT Observatory, and in PHM-Ethics by updates to the Taxonomy and Dependencies Map. Furthermore, both projects contributed to the improvement

and standardization of ethical assessment procedures in the EU through development of validated interdisciplinary assessment methodologies and policy-oriented recommendations [7,8]. For these procedural outcomes to be successful, ethical assessment must precede technology implementation [2], made possible through widespread adoption of the projects' recommendations and assessment tools.

2.5. Context-sensitivity

A reason for the guarded value attached to the substantive outcomes of each project is the importance of context and stakeholder perspectives in understanding ethical issues and concepts. The predictions of each project therefore quickly lose 'currency' as ICT development changes over time [1, p.26].

Both projects share a concern with the lack of context-sensitivity in current governance approaches, which reflects hermeneutic epistemological and ontological commitments [9–11]. Norms are prescriptive statements given content and relative importance within specific contexts by stakeholders. Current governance approaches treat norms as statements separable from context, amenable to logical deduction [1,12]. Norms and ethical issues are often formulated in committees by experts far-removed from day-to-day practice, and are limited by the expert's frame of reference, leading to the exclusion of relevant perspectives and emphasis on sectoral and specialist interests [1]. Such a situation is unacceptable in societies that claim to be democratic.

Approaches which seek to provide general specifications of norms applicable across multiple contexts therefore fail to capture the importance of context in articulating and comprehending norms. In light of this concern, emerging technologies need to be assessed within specific contexts of use, in which stakeholders unique to that context can be identified and included in development and regulation. Through civil participation, ethical, social and legal issues of practical importance can be identified and headed off. ETICA and PHM-Ethics sought to redress the imbalance in current governance through the creation of assessment methodologies and tools which emphasize context-sensitivity and broader stakeholder involvement in research, development and regulation. Both projects therefore respond to the ethical challenges of the future by preventing the emergence of ethical problems.

3. Research Methods

As both projects aimed to contribute to European discourse through the creation of tools for the ethical assessment of emerging technologies, their methods must be understood in terms of development and validation of the methodologies. Innovation development is viewed as an open-ended process, which necessitates reflexive assessment tools open to revision on the basis of unforeseen technologies and ethical, social and legal implications [13]. Initial identification of PHM and emerging ICTs, and initial understanding of their normative implications was necessary to build the first iteration of the tools, which are intended to be updated as technological and ethical developments occur [1,2]. The initial research was condensed in the course of both projects into practically useful assessment tools [2].

3.1. Identification of Emerging Technologies and Ethical, Social and Legal Issues

Review of relevant academic and governance literature on ethical, legal and social perspectives provided the groundwork in both projects for identification of technologies, applications, and their implications. ETICA created descriptions of each technology consisting of defining features, applications in development, areas of use and ethical, legal and social issues identified in the literature. The identification of technologies and issues was descriptive, led by a dual discourse analysis of academic literature in the field of ICT ethics, as well as EU governmental and funding publications [14–16]. Technologies were arranged in a matrix which assisted identification of ethical issues. Bibliometric analysis of the reviewed literature indicated avenues for ethical analysis through identification of the frequency with which ethical concepts appeared, as well as relationships between technologies and concepts in the literature [15].

PHM-Ethics consisted of three phases, the first of which identified ethical, psychosocial and legal implications of emerging PHM applications. Issues were identified through a descriptive literature review and empirical research, which contributed to the creation of the Taxonomy and Dependencies Map.

The PHM-Ethics Dependencies Map identifies specific stakeholders and areas in which ethical, social and legal issues may arise in the future. 'Dependencies' were identified between nodes representing the stakeholders, application areas and relationships relevant to implementation and regulation of PHM (in the EU). Several levels of relationships were identified in the map, with the highest level consisting of connections between: People, Society, Government, Operation (of the technology), Law, Medics and Allied Professionals, Health Informaticians, Social Scientists and Philosophers, Healthiness, and PHM Instruments.

The scope of the potential ethical, legal and social issues of PHM is incredibly large as reflected in the Dependencies Map, which necessitated the creation a 'critical dependencies map' of issues and relationships of critical importance which should be considered before the development cycle ends [17]. A similar approach was taken in ETICA in creating an enabling hierarchy of technologies, with potential ethical implications ranked in terms of severity. Although both projects relied upon descriptive methods for identification of technologies and issues, thereby avoiding adoption of a single ethical perspective, some prescription was necessary in assigning relative importance to each finding. In both cases issues were ranked according to severity, conceived in terms of likelihood of occurrence in the near future, or of such normative importance as to necessitate immediate attention to prevent widespread or particularly catastrophic ethical problems. The influence of prescription in the identification and evaluation of ethical issues should not be underplayed; classifying a predicted outcome as 'ethical' necessarily invokes norms. Prescription does not, however, represent a weakness in the initial findings of the projects; rather, it is a necessary component for an initial normative overview of PHM and emerging ICT ethics, provided by expert members of the consortia.

3.2. Critical Review of Current Governance

In both projects EU legislation and approaches to ethics governance (e.g. ethics review committees, FP7 programs, Technology Assessment) were critically reviewed to identify procedural gaps and limitations to overcome through development and

implementation of the assessment methodologies [16,18]. The reviews revealed both short and long-term problems related to context-sensitivity, reliance upon expert opinions in governance, ethical “blind spots” which preclude consideration of emerging ethical issues, and various legal challenges to be overcome in implementing PHM and emerging ICT, such as liability law reform [1, p.5; 2]. Areas of conflict were also identified between values and principles embodied in EU directives and the ethical issues identified earlier in the project; these legal barriers are predicted to require legal reform before implementation of the technologies can proceed [16,18], otherwise conflicts in values between EU institutions and stakeholders in ICT development and deployment will create ethical problems [19].

3.3. Initial Ethical Analysis

Following the reviews of ethical, legal, social and governance issues, ethical analysis occurred in both projects to create an initial overview of the ethical implications of PHM and emerging ICT. Different methods of analysis were used in each project, although similarities did exist. Both projects created and validated assessment methodologies for this purpose, meaning assessment tools were created and then used (and tested) to develop initial ethical understanding of the projects’ respective fields.

Future ethical scenarios are often represented through thought experiments or case scenarios, which reduce the technology to its ideal or defining characteristics for ethical analysis. This approach was used in ETICA (technology descriptions) and PHM-Ethics (case scenarios). Idealized versions of the technologies and applications in development were considered in imagined contexts of use. While unfailing predictions of the future remain necessarily out of reach, this type of illustrative analysis was helpful in relating possible futures to current practices and concepts to ensure relevant issues were not ignored.

3.3.1. ETICA

Ethical analysis in ETICA focused on describing, evaluating and ranking the ethical issues identified earlier in the project through analysis of the matrix of emerging applications. Technology-level analysis identified broad ethical issues not yet on the agenda of EU policy-makers and developers.

A separate ethical analysis was conducted for each technology guided by the technology descriptions [1]. Defining features and application areas and examples were discussed for each technology, followed by cross-referencing the bibliometric analysis to ensure all related concepts and issues were considered.⁷ A concluding discussion was then written which summarized the possible ethical issues and their relative severity for each technology. This process was not conducted entirely by a single consortium partner; rather, ranking occurred in a second round of analysis focusing on ethical standards, principles and values identified in EU and national level ethical reviews, advisory reports and policies [16,19,20]. The second analysis used legal, gender, ethical and Technology Assessment perspectives in evaluating the technology descriptions and the results of the initial ethical analysis, which was based on the literature review, bibliometric and technology description analyses [15].

⁷ Defining features and applications were constructed in Work Package 1, and are available for review on the ETICA web-site.

Ranking was necessary to ensure issues of immediate or severe importance to policy-makers were highlighted. Common issues, principles and concepts were identified across the range of technologies, which is unsurprising considering the enabling technological hierarchy established in ranking the ethical issues [19].

3.3.2. PHM-Ethics

The second phase of PHM-Ethics was dedicated to the assessment of PHM from ethical, legal and psycho-social perspectives. Assessment tools from ethical, legal and psycho-social perspectives were developed and used for this purpose. In comparing analysis in PHM-Ethics and ETICA, the most relevant feature is the ethical assessment tool (EAT), which is based upon interactive Technology Assessment (iTA) [6].

Development of the methodology required adaptations to iTA to meet the challenges of policy-oriented ethics research related to context sensitivity and stakeholder participation. The EAT incorporates an open-ended (revisable) questionnaire in which stakeholders identify (the relative importance of) moral values and principles affected by a PHM application in a specific context. Crucially, the EAT separates participatory evaluation from theoretical analysis. Ethical analysis is limited to experts—the methodology is therefore participatory only so far as stakeholders help develop context-sensitive understanding by identifying, evaluating and ranking moral values and principles, ensuring a wide range of perspectives are considered in ethical analysis.

3.3.3. Comparison of Analytical Methodologies

The approaches taken in PHM-Ethics and ETICA stand in contrast to iTA, in which experts act as discourse moderators, “setting the horizon for contexts, not determination of issues, based upon the interpretation of narrative information” [1]. Ethicists therefore structure the discourse with reference to ethical theory and concepts, but do not determine the ethical issues or their relative importance—this task is left to the stakeholders (e.g. users, developers, policy-makers). ETICA goes beyond iTA in encouraging experts to not only moderate discourse but to “construct the norms” which condition a specific context. Ethical issues can then be predicted by comparing the constructed norms to knowledge of the R&D process of a specific application. The issues can then be resolved through R&D. This role is slightly different than the one prescribed in PHM-Ethics because appropriate resolution of foreseeable ethical issues is left to stakeholders in R&D in ETICA, whereas experts conducting PHM-Ethics’ EAT both identify ethical issues and recommend solutions through policy and development [1,6,7]. Importantly, both projects identify experts as crucial in grasping the context-sensitive interpretation of norms, values and principles in ethical analysis. Such an approach was found to be missing from many current governance frameworks [2,7].

Despite the analytical role of experts in both projects, a single ethical perspective was not dominant in ETICA or PHM-Ethics—theoretical insights from normative frameworks such as utilitarianism, deontology and virtue ethics were used where appropriate. Issues were not cast in terms of controversial concepts such as rights, human dignity, risks or moral obligations, although these and similar concepts often appeared in current EU legislation [16,18]. This approach ensured analysis was not limited to the issues considered important by consortium members.

3.3.4. Validation of Identification and Analysis Phases

The assessment tools and initial ethical analyses of both projects were validated through empirical research which assessed the relative importance of the issues to stakeholders. The empirical studies also contributed previously unidentified ethical issues and norms. ETICA conducted two focus group sessions with members of the public, an online questionnaire of FP7 project coordinators, and a Technology Assessment conducted by project partners [1]. PHM-Ethics validated all five of its components through consideration of case scenarios at consortium meetings, although validation was impossible for the report on legal and ethical constraints due to its descriptive nature [8]. Improvements were made to the EAT through small-scale interviews. The psycho-social module was also validated through empirical research with students at consortium universities [8,13].

4. Initial Ethical Issues

As identified through the initial ethical analyses, the ethical implications of PHM and emerging ICTs mostly consist of pre-existing ethical issues, principles and concepts, as opposed to genuinely new contributions [7,15,18]; however, the need for extensions or other revisions to pre-existing concepts and principles was noted [1,15]. Although ETICA studied eleven technologies in total, significant overlap was found between its analysis of Aml and PHM-Ethics' analysis of PHM.

ETICA classified Aml according to six defining characteristics:

"(1) embeddedness and invisibility of the sensors and computational devices, (2) interconnectedness of the sensors and computational devices, (3) the Aml system is adaptive, that is, the system adapts to its circumstances, (4) the system is personalized, tailored to the needs of its users, (5) the system is anticipatory, that is, it can anticipate its users needs and desires, and (6) the system is context-aware, it can recognize specific users and its situational context and can adjust to the user or context" [15, p.37].

In ETICA, privacy, surveillance, data protection, autonomy, freedom, equity and liability were seen as important ethical concepts in understanding the implications of Aml [15], and by extension PHM. Every one of these topics was reflected in PHM-Ethics. The more intense focus of PHM-Ethics could therefore be seen as reinforcing the validity of the conclusions of ETICA related to Aml.

Collection, storage, transfer and fair use of data took central importance in both projects. Contextual surveillance of health and daily behaviors made possible through both technologies is a major problem for the privacy of users [15]. Profiling, behavior monitoring and social sorting are made possible through such surveillance [15,21,22], which has been compared to a modern panopticon [23,24] due to its 'long memory' and influence on the behavior of users [18]. The sensitivity of data brought into existence by PHM creates the potential to peer deeply into the personal lives of users, revealing information about their health which is seen in legislation as a sensitive topic requiring extra protection [25,26]. Unforeseen combinations of PHM applications may create opportunities for non-health monitoring, in which the combination of monitoring data about multiple individual parameters provides insight into daily behaviors and the user's private life [17]. This extension of PHM systems to new users and unintended uses is referred to as 'usage creep' [17, p.20; 27]. At its most extreme, usage creep

could lead to biometric profiling through the linkage of biometric data with PHM and Aml systems, enabling tracking of individuals [15,28]. All of these imagined scenarios involve infringement of expectations of privacy, and further complicate protection mechanisms such as informed consent, which rest upon the adequacy of knowledge about risks and benefits. Trust in 'systems' is considered a crucial element in avoiding perceptions of surveillance in PHM, justified or not [15,17,29,30].

PHM and Aml may also have implications for user autonomy, defined as "the ability to construct one's goals and values, and to have the freedom to make one's decisions and perform actions based on these decisions" [22, p.94]. While the scenarios imagined in ETICA are relatively benign, such as a 'smart refrigerator' ordering undesirable groceries, the implications for PHM are more severe, ranging from risks of social isolation to technological dependency in carrying out daily behaviors [22,31–35]. In both cases the user experiences the technology infringing upon or removing their control over a situation. The possibility of autonomy infringements increases as emerging technologies are used to replace humans in mundane or difficult activities, a problem recognized in ETICA's analyses of Robotics and Ambient Intelligence [15]. Replacements are enabled by (for example) the intentions of the developer or perceived socioeconomic benefits (e.g. cost savings in healthcare) [6,15]. If problems occur in situations in which human work is supplemented or replaced by emerging technologies, it is also unclear where liability rests for the failure of the system [15].

Equity was also a concern in ETICA, with relevance for ongoing assessment conducted by PHM-Ethics. If PHM comes to be used widely for preventative purposes, the predicted benefits to health associated with early diagnosis could further widen the healthcare gap between developed and developing nations [15]. An argument can be made that equitable distribution is required, which guarantees that PHM is available regardless of socioeconomic status or nationality.

A majority of attention in PHM ethics literature is dedicated to applications for the elderly and chronically ill, particularly Ambient Assisted Living [3,36]. When focusing on these demographics, the ethical implications identified tended to describe issues of "ageing and technology," as opposed to personalized health monitoring as a unique development in ICT and healthcare [3]. However, ethical assessment of PHM must consider other demographics because the target audience of PHM is manifold, as seen through intended uses in both managing existing conditions and preventing or hastening the diagnosis of developing conditions [3].

The stakeholders in the ethics of PHM are not limited to users alone; family members [37], medical personnel, data custodians, and a variety of institutions including insurers and telecommunication companies are involved in the collection, movement and usage of PHM data. This much is reflected in the literature reviewed in PHM-Ethics, which typically focused on the impact on social systems rather than users [3]. Engagement of these often ignored stakeholders in future ethical assessment is necessary according to the methodologies developed in these projects.

5. Recommendations and Outcomes

The defining feature of future-oriented ethics governance and research in the EU is that the inherent uncertainty of the future precludes confident identification of the ethical, social and legal implications of emerging technologies. Furthermore, norms and

implications occur in specific contexts, and rely upon stakeholders for meaning and relative importance. Current governance approaches (and the experts responsible for them) do not always recognize these limitations. ETICA and PHM-Ethics both aimed to improve this situation.

Evidence of the shortcomings of existing governance can be seen in the gulf between issues of importance as identified by experts and civil society. The ETICA focus groups mentioned above involved members of the public, who were introduced to emerging ICT and asked to identify and evaluate moral values, principles and ethical implications. While this step served to validate the results of the identification phase of ETICA, it also revealed discontinuity between public and expert concerns [1]. The gap reveals potential problems with the relationship between researchers and civil society. It may be that sufficient effort is not dedicated to the dissemination of findings (in comprehensible language), or that the public is not interested or unaware of the existence of such research. Researchers may also be failing to familiarize themselves with public opinion through (for example) empirical research.

Regardless of the specific cause(s) of the gap, both projects sought to lessen it through the creation and dissemination of assessment methodologies and governance recommendations which require public engagement and participatory development. These efforts can be placed within practice-oriented and participative trends in ICT research in recent decades, seen best within approaches such as Participatory Technology Assessment [38,39] and Empirical Ethics [40–42], both of which engage members of the public in the assessment (and development) process.

The desire for improvement of governance schemes is reflected in the outcomes of both projects, which focus on the limitations of current approaches. In comparison to PHM-Ethics, ETICA provided broad policy and development oriented recommendations to create an environment in which proactive ethical assessment is possible. ETICA's recommendations are aimed at policy-makers as well as industry, researchers and CSOs, recognizing their diverse roles in ICT governance: policy-makers formulate regulatory frameworks which govern ICTs as they emerge, while industry, researchers and CSOs are "innovators and users of ICT...who ought to be proactive in their consideration of ethics" [1, p.3]. In contrast, the recommendations made by the more tightly focused PHM-Ethics project are, although primarily policy-oriented, focused mainly on the specifics of stakeholder engagement and context-sensitive assessment. The recommendations of PHM-Ethics therefore operate best in a supportive environment of the kind recommended by ETICA, and flesh out the latter's broad recommendations with practical guidance and tools. With that said, PHM-Ethics' recommendations operate at a broader level as well by emphasizing the importance of establishing a regulatory framework which encourages "interactive ethical assessment," in which contextual understanding of norms and stakeholder participation in assessment and development take primary importance.

5.1. ETICA Recommendations

The ETICA project aimed separate recommendations at policy-makers and industry, researchers and CSOs.⁸ An institutional framework was detailed which assists in delegating the responsibilities for ethical assessment across stakeholder groups through discourse [1]. In general, policy-makers were recommended to establish an

⁸ Full details of ETICA's recommendations can be found in [1,7].

environment in which participatory ethics governance is required and supported, while industry, researchers and CSOs were encouraged to use the tools provided by policy-makers to undertake ethical assessment before implementation of emerging ICTs. The recommendations detail the responsibilities and activities required in conducting an 'Ethical Impact Assessment' prior to implementation of an emerging ICT [1].

Policy-makers were recommended to (1) provide a regulatory framework which will support Ethical Impact Assessment for ICTs, which encourages industry and government to recognize and respond to the ethical implications of technological developments; (2) establish an ICT Ethics Observatory, which updates the initial ethical assessments performed by ETICA and disseminates updated analysis alongside theoretical and normative information required for Ethical Impact Assessment; and (3) establish a forum for stakeholder involvement, which institutionalizes the discourse between industry, policy-makers and civil society to ensure a broad range of perspectives and societal concerns are reflexively considered in development and ethics governance.⁹ The rationale for these recommendations is that the establishment of an "institutional framework, background, repository and societal discourses" creates favorable conditions for the "incorporation of ethics and reflexivity into technical work and application usage" [1].

Once favorable conditions are established, industry, researchers and CSOs are recommended to (1) incorporate ethics into ICT research and development through discourse with a diverse range of stakeholders in which ethical issues are identified and norms specified, demonstrating that fulfillment of "legal requirements is not always sufficient to address ethical issues"; and (2) facilitate ethical reflexivity in ICT projects and practice, affirming the context-dependency and transience of ethical issues, solutions and norms. Ethical implications of future technologies are most effectively solved through prevention rather than reaction [4,43], so the incorporation of an ethical perspective in development and research is crucial to ethically responsible innovation.

5.2. PHM-Ethics Recommendations

In a similar way to ETICA, the PHM-Ethics project identified problems with current ethics governance which can be resolved through implementation of participatory assessment and context-sensitive understanding in ethics governance, achieved through discourse with a variety of stakeholders. These recommendations can be enacted with national and EU policy. However, through dissemination of the developed assessment tools, PHM-Ethics aims to improve current governance through a change of mindset, rather than solely through policy advice.

Additionally, cross-border legal barriers to the optimal implementation of PHM were identified which suggest organizational, regulatory, ethical and legal solutions. In the short term, medical liability legislation, working conditions for healthcare professionals, informed consent and electronic health records require clarification and revision in response to the challenges of cross-border PHM usage. In the long term, policy-makers need to reconsider national and international positions on respect of privacy, the relationship between health professionals and patients, and economic and organizational challenges, especially those relating to reorganization of healthcare and

⁹ The upcoming FP7 research project CONSIDER (Civil Society Organisations in Research Governance, GA 288928) aims at establishing a stakeholder forum of the kind described here. Consortium partners from the Centre for Computing and Social Responsibility at De Montfort University are involved in the project.

the (perhaps troubling) introduction of a relationship between industry and patients in healthcare [18]. While specific solutions are not suggested, the details of each challenge are explored in the PHM-Ethics' Report on Ethical and Legal Constraints [18], which suggests avenues forward for policy-makers, researchers, developers and other stakeholders.

5.3. Realization of Recommendations

The majority of recommendations in ETICA for policy-makers and industry relate to the creation and involvement in an environment supportive of ethical assessment of emerging ICT. The activities undertaken in each research project have already contributed to some of the specific recommendations offered in ETICA. These activities, along with the relevant recommendations, are highlighted here.

ETICA recommended the establishment of a regulatory framework, "to provide appropriate tools and methods to identify and address ethical issues" [1]. A stakeholder forum which utilizes these tools is recommended, in which "consensus concerning good practice in the area of ICT and ethics" can be reached by bridging the gap between civil society, experts and policy-makers [1, p.6]. PHM-Ethics contributed to both recommendations with its tools for assessment, which may prove to be applicable to emerging ICTs beyond PHM. The PHM-Ethics toolbox could therefore be utilized by policy-makers in creating a supportive regulatory framework, and establishing the methodology of a stakeholder forum.

The creation of an ICT Ethics Observatory that provides "a community-owned publicly accessible repository and dissemination tool of research on ICT ethics," which gives "examples of approaches and governance structures that allow addressing ethical issues" has been started by ETICA in its maintenance of a project web-site (<http://ethics.ccsr.cse.dmu.ac.uk/etica>) [1, p.6]. The tools provided by PHM-Ethics could be included on the site as an example of a context-sensitive, participatory approach to governance. Both projects emphasize the importance of keeping the Observatory current, through updates to the PHM-Ethics taxonomy and dependencies map reflecting new developments in ICT, and the application of ETICA's methodology to future emerging ICT. This is being partly realized by an ICT Ethics Observatory which is being developed in the context of a new UK EPSRC funded project on a Framework for Responsible Research and Innovation in ICT (<http://www.responsible-innovation.org.uk>), and will be further developed in the upcoming RESPONSIBILITY (Global Model and Observatory for International Responsible Research and Innovation Coordination, GA 321489) project.

The industry-oriented recommendations made by ETICA are met in part by the methodological contributions of PHM-Ethics. ETICA recommended incorporation of ethics into ICT research and development to create context-sensitive specifications of ethical issues and norms through stakeholder engagement [1]. The EAT requires this type of discourse, in which as many stakeholders are engaged as possible, to include at least developers and potential users. Stakeholder discourse, in which norms, values and principles can be exchanged, is therefore encouraged under PHM-Ethics, which is unsurprising considering the influence of interactive Technology Assessment in the development of the EAT.

5.4. Complementary Assessment Tools and Implementation in EU Governance

While ETICA provided an extensive set of policy and industry oriented recommendations, its assessment tools are somewhat less useful once discourse has been established between stakeholders. This situation is perhaps unsurprising—ETICA was not designed to provide a conclusive list of emerging ICTs and their ethical implications, but rather to act as an “early warning system” within broad policy advisory schemes [7]. This gap has been met by PHM-Ethics, with its focus on providing evidence for evidence-based policy. ETICA and PHM-Ethics maintained complementary and occasionally overlapping research agendas: the former at the level of policy and general foresight, the latter at the level of context-specific ethical assessment and identification of general ethical issues and themes relevant to that context.

The different levels of assessment are reflected in the ethical assessment tools developed in each project. While ETICA developed a broad early warning methodology based on foresight, PHM-Ethics’ ethical assessment tool consists of two parts: in the first, stakeholders (technicians, politicians, health care workers, users) are interviewed with a questionnaire consisting of generic questions relating to the characteristics, aims and implications of emerging technologies, which encourage stakeholders to identify and evaluate context-specific norms and principles [6]. The interview data, conceived of as moral values relevant to ethical assessment, is then entered in a matrix of ‘moral values to be realized’ and ‘stakeholders’. The matrix assists in the identification of ethical issues relevant to a specific application or context, which must then be specified and balanced by stakeholders. The tool is meant to be used before widespread implementation, meaning the outcomes of the matrix can inform development of the application in question [13].

If the PHM-Ethics toolbox proves to be applicable to other emerging technologies, then it can take up the work of ethical assessment where ETICA leaves off. Specifically, it provides an assortment of modules to identify and evaluate ethical issues arising in specific contexts through discourse with stakeholders. While these tools are currently limited to PHM, their underlying methodologies can be tested with the technologies highlighted in ETICA. If successful, PHM-Ethics has created a set of tools for context-sensitive ethical assessment of emerging technologies, which builds upon and encourages the sort of discourse recommended by ETICA. The two projects are therefore complementary; the former provides a methodology for ethical assessment and solutions at a context-specific, development stage, while the latter provides a methodology for early warning of ethically relevant emerging technologies at a policy level. PHM-Ethics can therefore build upon the findings of ETICA in developing its tools for context-specific ethical assessment through recognition of broader ethical issues. If considered together in revising EU ethics governance, the two projects form a multi-level package of policy and practice oriented assessment methodologies.

6. Conclusion

ETICA and PHM-Ethics have been shown to be complementary in their aims, methods and outcomes. Apart from developing a knowledge base and assessment methodology, a change in mindset towards ethical assessment is required to realize the integrative

aims of context-sensitive assessment promoted by both projects. Reflexivity is required, in which norms are understood from the perspective of a particular stakeholder in a specific context. Current governance emphasizes the triumph of “the better argument,” favoring abstract, universal, context-free arguments to integrate different perspectives. In place of the dominance of abstraction, reflexive understanding, stakeholder participation, and context-bound norms must be given equal consideration in integration. Without a reflexive mindset, the ideal of context-sensitive governance will remain elusively out of reach.

Despite having officially completed research activities in 2011, both projects continue to engage in dissemination activities in an attempt to change the mindset and methodology of ethical assessment of emerging ICTs in the EU. Each consortium maintains a web site, with ETICA’s offering acting as groundwork for an ICT Ethics Observatory which is being developed in the context of a new UK EPSRC funded project on a Framework for Responsible Research and Innovation in ICT (<http://www.responsible-innovation.org.uk>). Interdisciplinary validation workshops and dissemination conferences have occurred across the EU, complemented by numerous peer-reviewed journal and conference publications [1,2]. It would appear that consortium partners in ETICA and PHM-Ethics take their obligation to contribute to responsible innovation in the EU through improvement to ethics governance and ethically-sensitive technology development seriously. However, going forward the projects should emphasize the relationship between their outcomes, which when combined form a robust package of methodologies for ethical assessment of emerging ICTs.

7. Acknowledgements

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Appendix 18: Manuscripts under Review

The manuscripts provided below are under review for journal publication at the time of submitting the thesis. The first, 'The Ethical Implications of Personal Health Monitoring', is a piece co-authored with N. Ben Fairweather, Mark Shaw and Neil McBride based on the results of the literature review taken from Chapter 3, which has been accepted for peer-review by the International Journal of Technoethics. The second, 'How to Shape a Better Future?', is a piece co-authored with Bernd Stahl and N. Ben Fairweather which provided content for the discussion of empirical ethics, discourse ethics and uncertainty in Chapter 7. The manuscript has been accepted for peer-review by Science, Technology & Human Values.

The Ethical Implications of Personal Health Monitoring

ABSTRACT

Personal Health Monitoring (PHM) uses electronic devices which monitor and record health-related data outside a hospital, usually within the home. This paper examines the ethical issues raised by PHM. Using a study of 339 articles concerning PHMs, nine ethical issues are identified. These include privacy, autonomy, obtrusiveness and visibility, stigma and identity, medicalization, social isolation, delivery of care, and safety and technological need. The issues around each of these are discussed. The system / lifeworld perspective of Habermas is applied to develop an understanding of the role of PHMs as mediators of communication between the institutional and the domestic environment. Furthermore, links are established between the ethical issues to demonstrate that the ethics of PHM involves a complex network of ethical interactions. The paper extends the discussion of the critical effect PHMs have on the patient's identity and concludes that a holistic understanding of the ethical issues surrounding PHMs will help both researchers and practitioners in developing effective PHM implementations.

Keywords : Personal Health Monitoring, Literature Review, Habermas, System / Lifeworld, Ethics

INTRODUCTION

The conjunction of wireless computing, ubiquitous internet access and the miniaturisation of sensors has opened the door for technological applications in medicine which allow the remote monitoring of medical conditions and relevant physiological parameters. Such technologies, examples of which are given in Table 1, come under the heading of personal health monitoring (PHM).

Insert Table 1 here

PHM refers to any electronic device or system that monitors and records data about a health-related aspect of a person's life outside a hospital setting. To qualify as PHM a device must be capable of transferring data to a third party and be usable by a layperson outside a traditional medical environment such as a hospital. PHM is

related to “telehealth and telecare” (Kaplan and Litewka, 2008) and “assistive technologies” (Demiris and B. Hensel, 2009; Tiwari et al., 2010), and covers various technologies including “ambient intelligence” (Kosta et al., 2010), “somatic surveillance” (Monahan and Wall, 2007), “wearable health sensors” (Arnrich et al., 2010; Lymberis, 2005) and “surveillance technologies” (Niemeijer et al., 2010).

The applications of PHMs are wide, and can include physiological monitoring in healthy people, for example, for monitoring the body’s response to sports activities, but the primary focus of PHMs, which will be pursued in this paper lies in the support of patients with long term chronic conditions such as chronic pulmonary obstructive disease, diabetes, asthma and heart disease. Such conditions often require long stays in hospital or hospitalization at short notice. The use of PHMs enables patients to stay at home and live a more normal life outside the restrictions of institutionalization. PHMs are attractive technologies for hospitals to reduce costs and free up hospital beds.

However, moving patients to their homes and implementing PHMs to enable monitoring by the hospital changes the dynamic of the relationship between the patient and the hospital and embeds aspects of the institution into the patient’s home environment. Interventions may be done remotely and large amounts of medical data may be transferred from the home to the hospital. This may result in what Habermas (1992) terms the “colonisation of the lifeworld” in which the private concerns and activities of the patient become the concerns of the public institution which draws information from the patient’s private world and seeks to influence and change activities within the patient’s home environment.

This dynamic connection between the hospital and the home changes the ethical climate (Huff et al, 2008) and requires the addressing of a variety of ethical issues. It creates a requirement for a new framework to address the social and ethical effects of PHM implementation. A first step towards such a framework will involve the identification of the ethical issues associated with PHM, which may subsequently lead to new tools for the evaluation of the social and ethical effects of PHMs in the field.

Three approaches to identifying the ethical issues may be considered. Firstly, the technology can be examined, characterised and analysed. This is the approach of the EU FP7 PHM-Ethics project (grant agreement no.: 230602) which sought to classify technologies and draw ethical issues from that classification (PHM Ethics Consortium, 2012). A second approach is to conduct fieldwork and question patients, carers and their clinicians. This approach is the focus of a current study (Mittlestadt in preparation). A third approach involves examining applications through practitioner and researcher literature to see what ethical issues have been raised.

This paper reports the results of such a literature search which examined 339 articles with the aim of uncovering practitioner and researcher ethical concerns and presenting them in an ordered classification.

The outcomes of the literature search and classification are then used as a basis for developing an understanding of the role of PHM as a mediator in the patient / doctor relationship through a network of interlinked ethical factors which have a significant effect on the patient's identity as perceived by the patient and viewed by carers and healthcare professionals.

The next section describes the methodology by which ethical issues were derived from literature discussing PHM. The results of the analysis are then presented, and eight issues documented. The final section develops three perspectives based on the output of the literature review. The role of PHM is considered through the Habermasian lens of lifeworld and system. The ethical themes revealed from the literature study influence the delicate balance between lifeworld and system. In practical terms, the interpretation of ethical themes and the relationship between them is explored through the development of a cognitive map which helps identify the key foci to be considered in understanding the ethical impact of PHM and highlights the importance of interaction and links between ethical themes. Thirdly the importance of identity as a key point of influence of PHM is discussed. Finally it is concluded that the clinical potential of PHM may be undermined if social and ethical issues are inadequately addressed and the balance between the domestic practice within which the PHM resides and the institutional demands is not tackled.

This paper raises a number of novel issues. It is of value to researchers in providing a comprehensive literature review and identifying a theoretical direction for future research. Furthermore it offers practitioners critical insights as to where effort should be directed in developing sensitive, ethical approaches to the use of PHM in clinical interventions.

METHODS

Academic literature available in four databases (Scopus, IEEE, MEDLINE, and CINAHL) addressing the ethical implications of PHM was reviewed between May 2010 and September 2012. Attention was given to the discussion of ethical issues in each article, with the goal of identifying themes in the literature. The databases were searched to identify literature discussing ethical issues relating to the development and deployment of PHM. The search was limited to English language articles. Although most of the reviewed literature consists of peer-reviewed journal articles, other types of publications including commentaries, working reports, white papers and scientific books were included due to the exploratory nature of the review. Date restrictions were not placed on the search.

Search Procedure

Recognizing that "Personal Health Monitoring" is an emerging term not yet widely used in the literature, synonymous and related search terms were used including "somatic surveillance," "wearable body sensors," "personalized health," "pervasive

health,” “assistive technologies,” “ambient intelligence,” “health surveillance,” “ambient assisted living,” and “smart homes.” All articles matching the synonymous terminology were checked to ensure the technology under discussion matched the working definition of PHM.

Privacy, risk and security were excluded from the search queries because of the vast amount of literature written on these topics. To ensure the current discussion is comprehensive enough to allow for meaningful conclusions while still remaining a manageable size, and to give due attention to the uniqueness of privacy, risk and security as normative concepts, literature on these topics was reviewed separately (see: Mittelstadt et al., 2013).¹

Articles were reviewed to determine relevance to the current discussion, and were excluded if they only discussed development, implementation or technical specifications of PHM technologies.

Data Analysis

All articles underwent content analysis to identify treatment of the ethical effects of PHM. Key terms were identified, interpreted and combined into themes present across multiple articles in a process analogous to grounded theory (Strauss and Corbin, 1994). Words and passages were highlighted that appeared to refer to ethical issues or concepts, understood as areas of “right and wrong” or the clash of competing normative interests among stakeholders. Highlighted segments were then coded. Similar codes were assigned to themes as discussed in Section 4. The frequency with which codes appeared in the literature was used as a guide to the discussion of results.

RESULTS

A total of 339 articles were identified for review, 67 of which met the inclusion criteria of explicitly discussing ethical issues of PHM. Two sub-categories of PHM were identified during review of the literature, which are shown in Table 2. Five demographic groups of target users were also identified and presented in Table 3.

Insert Table 2 here

Insert Table 3 here

Insert Table 4 here

Through content analysis eight ethical themes emerged from the literature, which are reviewed in Table 4. Interpretation of findings and the designation of themes were discussed and agreed upon by the authors. The following is a thematic overview of the findings. Although the ethical themes emerged according to frequency, the overview does not merely highlight this frequency. Rather, the results discussed in the following sections were chosen for one of four reasons: (1) to draw attention to common interpretations of ethical themes and concepts, (2) to emphasize individual cases and issues that reveal unique ethical aspects of PHM, (3) to highlight studies with an in-depth analysis of ethical concepts and issues, and (4) to identify gaps in the discussion in need of further research. The presentation of results therefore focuses on the authors' analysis and interpretation of the literature.

Privacy

Despite exclusion from the search query, privacy was frequently discussed in the reviewed literature. The discussion of privacy mostly affirmed a separation of data and personal privacy, and viewed security as privacy-enabling.

Autonomy

Although autonomy was mentioned in several studies as an important ethical consideration, it was rarely elaborated as a concept. We interpreted it to include the right to make personal decisions (Demiris, 2009), a right to freedom (Brey, 2005) or a right to independence (Remmers, 2010). As implied by our interpretation, autonomy was often discussed in terms of freedom and independence, particularly in reference to assistive technologies (Remmers, 2010; Robinson et al., 2007; Zwijsen et al., 2011), smart homes (Brey, 2005; Remmers, 2010; Townsend et al., 2011) and residential care facilities (Dorsten et al., 2009; Zwijsen et al., 2011). The maintenance of independence in making decisions was interpreted as an issue of autonomy (Percival and Hanson, 2006; Remmers, 2010), especially in community care settings where opt-in/out systems may be necessary to maintain respect for the autonomy of individual residents.

A reliance on PHM among dependent users may also be viewed as an issue of autonomy and identity (or self-confidence) (Brey, 2005; Friedewald et al., 2007). PHM can help care for individuals, for instance by automatically alerting someone in emergencies or when behaviours fall outside normal parameters. By providing a "watchful safety net" PHM can reduce feelings of self-determination among users by reducing the need for self-reliance (Percival and Hanson, 2006; Remmers, 2010)—if there is a perception that a carer will be alerted if something goes wrong (Bowes et al., 2011; Demiris, 2009; Fugger et al., 2007), the importance of self-reliance is reduced. Dependent users may also experience changes to their role in user-carer relationships—Kenner (2008) suggests carers can make judgments and interventions based on PHM data which could potentially infringe upon the user's rights to privacy and autonomy

Obtrusiveness and Visibility

Obtrusiveness was identified as relevant to the acceptance and long-term use of PHM (De Bleser et al., 2011; Demiris and B. Hensel, 2009; Demiris, 2009; Townsend et al., 2011). Several studies employed a common framework of obtrusiveness in interviews and focus groups with users of smart home “assistive technologies” (Demiris and B. Hensel, 2009; B. K. Hensel et al., 2006; Tiwari et al., 2010). The framework defines obtrusiveness, according to 22 subcategories, as “a summary evaluation by a person based on characteristics or effects associated with the technology that are perceived as undesirable and physically and/or psychologically prominent,” meaning it is judged by the individual within a specific context. Although obtrusiveness appeared frequently as a term in the reviewed literature, the studies using this framework were alone in having a clear definition. The definition alludes to the distinction between physical and mental obtrusiveness as seen in non-medical ambient intelligence applications (c.f. (Brey, 2005)). According to these studies, a sense of obtrusiveness would lead participants to subvert the monitoring system in some way, for example by not stepping on pressure sensors (Courtney et al., 2007).

The related concept of visibility appears to refer to the degree to which a PHM device is noticeable by the user and other individuals, both at home and in public (Essén, 2008; Landau et al., 2010b; Robinson et al., 2007; van Hoof et al., 2011). Visibility differs from obtrusiveness in its emphasis on the public as well as private sphere. Characteristics affecting visibility included ease of use, size and weight (Landau et al., 2010b), which suggests a link to the notions of psychological and physical obtrusiveness, respectively. An example of PHM achieving low visibility occurred in two studies (Essén, 2008; van Hoof et al., 2011) in which the presence of PHM was forgotten following extended use.

The psychological disappearance of PHM can be problematic for in two ways. While disappearance may initially promote acceptance of the technology and preserve the meaning of the home (Courtney, 2008), users with cognitive impairment may eventually forget entirely about the monitoring equipment. This type of “covert” monitoring raises questions of consent (Bowes et al., 2011; Kenner, 2008), which was not recognized in all studies mentioning the phenomenon (c.f. (Van Hoof et al., 2011)). The issue of consent can extend to individuals entering the home of a monitored individual, which suggests the possibility of inadvertent monitoring (Neild et al., 2004), although radio frequency identification (RFID) tags have been proposed as a solution to differentiate between residents and guests (Neild et al., 2004).

Stigma and Identity

As a theme, Stigma and Identity refers to the implications of PHM for users due to the complex relationship between autonomy, visibility, stigma and identity. The relationship must be approached from both public and private perspectives to reveal the source of stigma and effects on user identity.

From a public perspective, PHM that is visible to others can cause the user to experience stigma, influencing self-esteem and self-identification as a patient. Such an effect was reported in a focus group study of elderly individuals in residential care (Courtney, 2008) in which participants felt that using PHM could lead to a feeling of frailty based on the public visibility of the devices. Residents were afraid that they would be judged for using PHM by other residents that did not need the devices, although it was suggested that the problem could be solved through aesthetic choices (Y.-H. Wu et al., 2012) or community wide implementation (Courtney, 2008). Attractive as the latter solution may be, it violates the principle that PHM solutions should be deployed to fit the individualized needs of the user to avoid “monitoring for monitoring’s sake” (Bowes et al., 2011), or pursuing monitoring as an end in itself (Coughlin et al., 2007; McLean, 2011).

From a private perspective, the relationship between autonomy and identity is important. Reliance on PHM raises questions about user identity, as PHM can affect the way a user perceives herself by fostering reliance on PHM for completion of daily tasks. This is especially true for elderly individuals wishing to retain independence and self-responsibility. By eliminating the opportunity to overcome obstacles associated with aging, PHM eliminates experiences that contribute to “a new sense [of] the meaning of life” for the elderly (Remmers, 2010). If overcoming challenges is central to the creation of identity as a life progresses as Remmers (Remmers, 2010) asserts, then PHM which fosters reliance for completing daily tasks imposes profound limitations on the lives of elderly users. Even without technological reliance, systems can influence how a user’s identity develops over time by automatically reporting risky or harmful behaviours indicative of frailty. These activities are often hidden by elders wishing to control the image presented to outsiders (Percival and Hanson, 2006), meaning PHM can erode the ability to manage public identity.

The public and private perspectives merge in considering expectations of behaviour. Users may feel pressure to behave in a certain way as a user of PHM, similar to the pressure placed on mentally impaired to conform to social expectations of behaviour (c.f. Page-Hanify, 1980). This pressure is both public and private—for example, others may actually hold expectations of behaviour for disabled persons, but even if such expectations do not exist the disabled person may self-impose behavioural limitations due to the perception that others hold such expectations. The same type of pressure can affect PHM users. If a device is (perceived as) publicly visible, the user may believe others harbour behavioural expectations (it matters not whether they actually exist, as the effect on the user is the same). Even privately visible devices could lead to (perceived) expectations of behaviour among the user’s family, friends and carers, as well as the user himself. Once a user has identified himself as (for example) “frail” (Courtney, 2008), the expectations of behaviour need not be external: if a user believes a “frail” individual to be someone that acts in a certain way, then the pressure to behave as such can be entirely internally imposed. Alternatively, users may believe the developers, administrators or the system itself harbour behavioural expectations. Smart homes have been shown to exhibit passive control over users, including the alteration of daily routines based on the presence of

monitoring (Tiwari et al., 2010). Such alterations have been traced to the perception of a “watcher” on the “other side” of the monitor (Essén, 2008), or the perception that the monitoring system is expecting behaviours within a “normal range.” This complex interaction between autonomy, visibility, stigma and identity may be dependent on a system’s degree of obtrusiveness, although such an assumption would need to be empirically tested.

Social Isolation

Concern over social isolation was present in several studies based on the possibility that visits from medical personnel and carers may be less necessary if daily monitoring at home is controlled by PHM (Demiris et al., 2004; Stowe and Harding, 2010; Tiwari et al., 2010; Y.-H. Wu et al., 2012). This situation occurs if PHM is used to “care” for patients in place of human carers, which can affect the frequency of visits and feelings of responsibility towards the patient. Studies involving older people have revealed a concern that PHM will replace personal and social interactions (Chan et al., 2008; McLean, 2011; Palm, 2011; Y.-H. Wu et al., 2012; Zwijsen et al., 2011) rather than supplementing them, while also reducing the amount of contextual information available when assessing a patient’s condition (Percival and Hanson, 2006), which suggests that the quality of diagnosis and care is diminished by the loss.

While a concern over increased social isolation was common, assistive homecare robots (Y.-H. Wu et al., 2012) and social networking features (Percival and Hanson, 2006) have been proposed as solutions. Classifying these interventions as solutions rests on the question assumption that human interaction can be adequately replied by technological interventions. According to Palm [4], if PHM is viewed by professional care providers as a replacement for social interaction among dependent patients, morally unjustifiable burdens may be placed on “informal carers” (family members, relatives, spouses) that are increasingly responsible for providing care and face-to-face interaction. Furthermore, although social networking can reduce feelings of isolation (Feenberg et al., 1996), in doing so it forces users to give up personal information to regain the social interaction lost to PHM.

Delivery of Care

A small number of studies discussed the impact of PHM on medical personnel. Two studies examining caregivers and power relationships was determined that “surveillance” in a social care setting can lead to new power relationships among professional caregivers and recipients, thereby affecting the activities and interaction during caregiver visits (Kenner, 2008; Vuokko, 2008). For example, if given access to monitoring data caregivers can ensure their patients are following recommended medical interventions or detect risky behaviours, thereby disrespecting the patient’s right to privacy and self-determination (Remmers, 2010). Concerns were also expressed over the impact on professional caregivers, as PHM was alleged to threaten job security among home care workers based on a perception that it may be

used as a tool of surveillance to expose human error, add to worker responsibilities (e.g. equipment maintenance) and complicate work routines (Tiwari et al., 2010). Concerns were especially raised that the influx of PHM data could cause “information overload” for nurses and physicians, who may be professionally obligated to review all available information about a patient (Kaplan and Litewka, 2008). These studies raise several important questions relating to the ethically acceptable level of workplace surveillance within the healthcare industry. Workers are clearly deserving of some level of privacy (c.f. (Lankshear and Mason, 2001)), yet this right may be necessarily eroded by the need to ensure the safety of patients.

Safety and Technological Need

Safety was described as an important factor in the decision to use PHM, and was often mentioned in connection with a ‘need’ for PHM. ‘Safety’ was interpreted as the detection and appropriate treatment of medical symptoms and behaviours. Several factors were identified as relevant to safety concerns among PHM users. One study identified a lack of contextual information in PHM data presented to physicians and nurses as a possible safety risk, potentially causing misdiagnosis (Kaplan and Litewka, 2008). Despite this, systems are often promoted as protecting or enhancing the safety of users (Nordgren, 2012), particularly among individuals with dementia and their caregivers (Lauriks et al., 2007). Safety appeared as a ‘goal’ that trumped concerns related to the other eight themes, particularly in studies of dementia caregiver attitudes, who often emphasize safety and peace of mind over other values, particularly privacy and autonomy (Landau et al., 2010b; Topo, 2009). Caution should be exercised in employing safety as a trump card in the decision to use PHM, especially for persons lacking the capacity to consent. Systems claim to generically enhance the safety of users (Nordgren, 2012), which ignores the fact that ‘safety’ is only given meaning in specific contexts by individuals with a variety of moral values and personal goals.

Despite the conceptual difficulties faced in the discussion of ‘safety’, it was frequently mentioned as the source of a ‘need’ for PHM among elderly and chronically ill individuals (Courtney, 2008; Melenhorst et al., 2004). While the content of the ‘need’ for PHM was often taken for granted, one study (Courtney et al., 2008) explored perceptions of need in depth, describing it as multi-factored concept built upon internal and external perceptions of health and well-being, as well as the fit of the specific technology to the user’s environment and current care regime.

Medicalisation

Medicalisation was rarely used as a term in the reviewed literature, although several studies described issues that can be interpreted as medicalisation of the home environment. In the context of the home, medicalisation occurs when a user is reminded of a health condition due to the presence of a monitoring system. In this sense, PHM introduces a medical aspect into the “experiences and meaning of home”

(Courtney, 2008), which is otherwise seen as place where privacy and identity are protected (Courtney et al., 2008). Multiple studies remind PHM developers of their responsibility in addressing the potential for medicalisation of the home (Bowes et al., 2011; Chan et al., 2008; Demiris and B. Hensel, 2009; Gentry, 2009), which may affected co-inhabitants as well as the user, although this aspect of medicalisation was not addressed in the literature.

DISCUSSION

Although medicalisation was rarely mentioned in the reviewed literature, it provides a conceptual link to make sense of the variety of ethical effects of PHM. Specifically, introducing medical awareness into a patient's private physical and psychological spaces demonstrates how PHM embodies values and expectations beyond those of the user. Medicalisation hints at a broader conceptual framework, based on Habermas' notion of the system / lifeworld divide, to connect and 'make sense' of the various ethical implications of PHM.

The System / Lifeworld Perspective

The use of PHM, in which data about a patient's condition is transmitted to a central point, provides benefits for both the hospital and the patient. The patient may gain peace of mind by knowing his safety is increased through constant monitoring, enabling advice on when an intervention is necessary and continuity in contact with clinical staff. As a result hospitals may be able to release beds, to work more efficiently and to reduce unnecessary admissions (cf. (Henderson et al., 2013). A delicate balance must be struck between two separate elements which Habermas characterises as the lifeworld and the system. The ethical themes addressed in this paper: privacy, autonomy, visibility, identity, social isolation, care delivery and safety are all influenced by the nature of the lifeworld / system relationship.

The lifeworld of the patient concerns the personal domain of the patient using PHM. The user has values, traditions, culture, accepted ways of behaving and being which are developed within the family and expressed within the home. A person's lifeworld is lived-out within personal environments and connected communities. The goal is one of belonging and safety within a living space. The lifeworld is concerned with quality of life and qualitative communication. There is often an emphasis on the private and the hidden. The lifeworld is a personal communication space with its own meaning and even language. The lifeworld encompasses a certain set of competencies, practices and attitudes which in the case of PHM may be most relevantly considered in terms of domestic practice. The lifeworld may be expressed in the home in terms of layout, and the arrangement of objects. At the heart of the lifeworld is a concern about who I am and who we are with a community.

In contrast, the system is not concerned with the personal, the private and the informal, but rather is concerned with the domain of institutions, power and

economic goals. It is concerned with the public sphere and the control of resources. The system discourse concerns concepts such as cost benefit analysis and quantitative communication. The system requires predictability and control hence there may be more of an emphasis on rules, structure and organisation.

The colonisation of the lifeworld occurs when the system seeks to exert its influence on the lifeworld and impinge controls and monitors. For example, when the use of computer games at home becomes a leisure industry measured through cookies on the home computer and delivering personalised advertisements into the home; when government seek to promote personal computer usage in the home, persuade people to have them and survey levels of usage; or when behaviour in the home concerning child discipline and smoking becomes a subject of legislation. The colonisation of the lifeworld by the system is characterised by an increasing quantitisation which may pit the social and personal life against the institutional and legislative.

However, it is not just a case of the system invading the lifeworld like colonial masters entering a tribal society. The quantitative systems within the medical environment – processes, bookings, money, boards of directors are ultimately legitimised by the lifeworld. In exploring the system / lifeworld relationship influence both ways should be considered, although the power balance may be in favour of the system's invasion of the lifeworld.

Within this perspective the role of PHM can be described as the communicative mediator of discourse between the system and the lifeworld. It bridges the communicative space between the lifeworld experienced at home and the wider concerns of society enshrined in the system. PHM has the potential to enable the colonisation of the lifeworld as the home becomes an extension of the hospital and the concerns of the institution affect attitudes, values and behaviour in the home. PHM enables the quantitisation of health parameters and home activity such that the needs of the system become the concerns of the home lifeworld.

PHM can provide for extension of a lifeworld and incorporation of aspects of the system in a lifeworld through video links from the home, for example. Hence PHM can increase personal communication, and develop safety, peace of mind and security such that the lifeworld is preserved and developed. However, PHM can also restrict the lifeworld, impinging the system's economic and power concerns on the individual lifeworld such that restrictions are placed or information demanded in order to maintain institutional structures. Hence PHM has the potential to act both as the repressive father, dictating behaviour and routine and demanding information for his own purposes, or the supportive mother offering both reassurance but also an environment which supports the autonomy of the patient.

PHM may compromise privacy because it provides the system with access to information about activities and behaviour within the patient's home, whether through monitoring through sensors in the home or through data entered by the patient into an Internet-connected interface as might be the case, for example, with COPD patients (Gale and Sultan, 2013). This data may potentially be misused and access to the data represents an invasion of privacy by the system. However, the

mere use of the PHM may enable a patient to be based at home rather than in a hospital where privacy will be much more restricted.

While autonomy is increased by the release of the lifeworld from the confines of hospitalisation, PHM still allows the system to invade the lifeworld and exert control through the quantisation and regulation of behaviour in the personal environment. Rituals and routines in the home become the concern of the system, as they become visible. They also may become more controllable with the presence of the PHM as physiological and behavioural characteristics are parameterised and measured. These measures, when provided to the system may result in intervention which regulates the behaviour of the user according to strategies and protocols legitimised by the system. It is in this sense that PHM is a surveillance technology—it allows for the evaluation of the user at a distance as a quantified set of measurements, decontextualised from the socially embodied person they represent.

The visibility of the PHM may also affect the user's identity, as PHM use becomes part of who they are, and affect behavioural patterns derived from the lifeworld. Behavioural patterns must be adapted meet the requirement of the PHM, whether that is in routines of monitoring by recording and transmitting physiological and behaviour data, or by routine of intervention, where therapies are conducted in response to the output of the PHM. The interpretation of what the numbers generated by PHM mean is most likely to be a system interpretation based on accepted protocol, research and clinical practice (cf. (Molewijk et al., 2003)). The interpretation then affects the lifeworld in making judgements about both physiological state and personal behaviour as to whether it is 'good' or 'bad', thus restricting the future opportunities of the user (cf. (Lyon, 2003)). Such judgement may be effectively ethical judgement, such that the system is imposing moral boundaries on the lifeworld.

While reducing the obtrusiveness of PHM might help minimise the effects on a user's identity and autonomy, expressed through behaviours, the system will still be affecting the lifeworld through remote evaluation, feedback and interventions. Those interventions are determined by the system, based on clinical information and accepted treatment protocols and on the needs of the system which may concern economic justification of service provision or funding (Froggatt et al, 2011).

The way in which the PHM acts as a conduit between the lifeworld and the system may support a medicalization in which the power imbalance between system and lifeworld, particularly amplified by the patient's dependency on the system results in an invasion of the lifeworld in terms which may be described as medicalization. Additionally, by connecting the system and the lifeworld, PHM may reduce isolation by legitimising contact with healthcare personnel and care workers (Gale and Sultan, 2013), or increase it by giving the impression that the PHM is 'caring for' the user in place of a human carer.

The interpretation of delivery of care through the lens of system/ lifeworld raises further issues. System concerns for control, regulation and economic management may not only be exerted on the patient as the user of PHM, but also on the care giver.

Economic demands to optimise the use of paid-for care may result not only in the reduction of contact hours but also in the management and control of care giver activities through the proxy of PHMs showing up how metrics change when the care-giver is present.

The PHM as a conduit between the system and the lifeworld also enables the colonisation of the lifeworld by the system's agenda for safety, which may be determined by regulations appropriate for institutions but restrictive in the context of the home environment, and by rhetoric concerning technological need which is determined more by the system's requirement for efficiency or revenue than the patient's clinical or personal needs.

PHM mediates communication between the patient and the institution. Critical discourse between the patient and the professional concerning the implementation of PHM, the interpretation of data and the behavioural and clinical interventions resulting from the PHM should result in greater understanding of how the patient's lifeworld can be supported and how the colonisation of that lifeworld by the system can be limited. Hence PHM is a subject for dialogue which will raise issues about care, independence, progression and treatment of a disease which extend beyond the technical confines of the PHM. In this way it may be that the learning and understanding that emerges from the implementation of the PHM is more important than the technology itself.

Linkage between ethical themes

The discussion above indicates that the themes elicited within this literature review do not constitute a catalogue of stand-alone concerns but are linked together in a network of interactions. Using the technique of cognitive mapping of the issues discovered around the themes, a composite cognitive map (Figure 1) has been constructed which links ethical themes.

Insert Figure 1 here

The map illustrates the web of influences between the ethical issues raised by the literature. Particularly two phenomena can be identified. Firstly, cascades of link such that an ethical issue may have an effect further down the line, the link for which may not be obvious. For example, PHM reliance, which is influenced by perceived safety need, may increase surveillance, which increases carer power and reduces patient autonomy. This type of study may enable researchers and practitioners to identify initial concerns, which through a cascade of ethical themes may exert undue influence on key ethical concerns. In the case of PHMs, perceived safety need eventually reduces autonomy and increases medicalization. In practice, a proper evaluation of safety needs which makes a realistic assessment of actual risks, and considers the patient's needs above those of institution and carers, may reduce the need for PHM and hence protect autonomy and privacy.

Secondly, certain ethical issues can be seen to be dominant and the target of other ethical influences. Hence in this literature review, the map suggests that autonomy is the key ethical issue, and is influenced by a range of other themes. Studies are therefore needed which examine the influence PHM has as a mediator in various medical relationships on the autonomy of the user or the subject, and the resulting implications for user autonomy of the system's colonising influence on the patient's lifeworld. With this said, privacy may also prove to be a key concept, as indicated by the quantity of results found in piloting this review which indicated the necessity of a separate review (see: Section #). Its position in the framework as shown in Table 1 is meant to reflect this aspect of the review.

It should be noted that for PHM, as for any technical intervention, it is context that matters and hence evaluation approaches should be developed which properly analyse the patient's situation in order to provide PHM interventions which are appropriate and beneficial. The study of networks also indicates that, besides concentration of influences in clusters around a particular node, single links to more distant aspects of the network may be critical in control. Here we note the link between autonomy and self-esteem, which itself is part of identity. We suggest that a critical ethical theme which needs development in the study of PHM ethics is that of identity, which is briefly addressed in the final section of this discussion.

Identity

Identity concerns a person's concept of who they are, the moral and social beliefs they embrace and how they relate to others. Identity works at a personal and social level; these influence each other (Fearon, 1999; Fearon and Latini, 2000). Biomedical advances such as PHM will affect people's identities (Foresight Future Identities, 2013). Attached to the person's body or installed in the personal environment, PHM becomes an extension of the person and an embodiment of the illness or the physical activity being monitored. A person's identity is often affected by an illness which becomes part of their identity, e.g. I'm a schizophrenic or I'm a COPD sufferer. The use of PHM may materialise the disease.

PHM will mediate relationships. Relationships such as husband, wife, father, mother of are core parts of our identity. PHM may strengthen connections with health workers and hence those workers become part of a patient's identity through the mediation of the PHM. Furthermore, the connection with the institution provided by the PHM may influence identity. The patient may now see being a patient of a particular hospital as a part of his identity even while at home. The colonisation of the lifeworld by the system, mediated by the PHM may impose institutional identity on the patient's individual identity. Interaction of system and lifeworld could be seen as creating a third identity which amalgamates the institutional identity, that is the public and exposed identity, and the domestic identity, the hidden private identity.

Since PHM influences and materialises key aspects of the patient's identity – illness, metrics, institutional relationships - clinicians and researchers should pay particular attention to the influence of PHM on the user's identity and how changes in identity influence dependency and autonomy. Furthermore, the persistence of data generated

by PHMs may make it more difficult to shake off a pathologically-based identity when PHM usage ceases and the disease is cured.

CONCLUSION

The developing technology of personal health monitoring has great potential to support improvements in healthcare. Data generated has the potential, using the techniques of business intelligence to generate useful clinical insights which may progress medical care. But an uncritical focus on the technology may result in a failure to observe the social and ethical effects of PHM, ultimately undermining its clinical potential. Therefore attention must be paid to the ethical effects of PHMs if real value is to be obtained.

In this study a survey of literature has served as a vehicle for identifying potential ethical issue with PHM including privacy, autonomy, obtrusiveness, identity, social isolation, safety and medicalization. However, the cataloguing of these ethical issues does not provide an adequate framework for sensitively managing the critical social and ethical effects of PHMs. Hence this paper progressed to developing key conceptual frameworks which will support researchers and practitioners alike in understanding PHM and deploying it in a clinically valuable manner.

The use of the system/ lifeworld frame clearly highlights the sensitive role of PHM. Rather than treating PHM as an isolated technical entity, with a focus on the ethics of the artefact, this study treats PHM as a communication conduit between the institutional life of the hospital and the domestic life of the patient, identified as the system and the lifeworld respectively. As such the PHM is not necessarily a technological source of ethical concerns. Rather it is a conduit for the flow of ethical concerns between the system and the lifeworld which inevitably alters the potency of such concerns and the ability of the user to manage them. Each of the ethical themes identified in the literature search may be interpreted in the context of the effect of the PHM on the relationship between system and lifeworld.

Additionally, this paper challenges the treatment of ethical issues in technology as standalone factors and through the analysis of the literature, identifies chains of cause and effect which generate complex networks of interacting ethical factors.

Finally, it cannot be escaped that health, illness, disability and treatments constitute a significant element of a person's identity and can become the predominant label a patient associates with themselves. Even the use of crutches has a powerful effect on how the patient view's their identity as well as the perception of observers, relatives and friend. How much more, then, will complex ICT, located in the home, determine the patient's perception of themselves and the carer's behaviour towards them, even if it is hidden on their body or embedded discretely in the domestic environment?

For researchers, a holistic understanding of the ethical issues of PHM, coupled with an understanding of the differentiation between the institution and the domestic practices provides a rich opportunity for field studies which will provide a deeper understanding of the role of advanced technologies in mediating social relationships.

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<p>Blood pressure monitoring - A patient with hypertension can use a wrist watch style device which monitors their blood pressure on a 24/7 basis (Laurance, 2011; Milenkovic et al., 2006). The monitor can create a log of blood pressure fluctuations throughout the day, and can automatically alert the user to heightened BP. The data can be analysed alongside a log of the user's behaviour throughout the day, which may reveal the effects of particular activities, foods, medications and other factors on the user's BP. This information may be usable by medical professionals to create a personalised treatment or lifestyle plan for the user.</p>
<p>In-vivo blood monitoring - Patients with a wide variety of disorders detectable through blood tests can make use of an in-vivo system which monitors blood quality in real time (Gaul and Ziefle, 2009; PositiveID, 2011; Pousaz, 2013). Possible uses include real-time blood glucose monitoring for diabetics, or early warning of heart attacks from the presence of indicator substances which appear in the blood immediately before an incident. The effect of medications could also be tracked in real-time, leading to more personalised health interventions.</p>
<p>Smart home monitoring - Homebound chronically ill and elderly persons can make use of smart home technologies, which can detect behaviour and health parameters through sensors installed in the home (Chan et al., 2009). Sensors could detect sleep patterns, activity levels, falls, and emergencies and automatically alert family members or medical professionals when an emergency occurs, or a problematic health or behaviour pattern emerges. The effect of medications could also be tracked through behavioural data. Information gathered by smart home sensors could be used to evaluate the care needs of 'at-risk' patients, and keep a 'watchful eye' on them when human carers are unavailable, which supports ageing at home for longer than would be possible without such monitoring.</p>
<p>Wearable sensors - 'Smart clothes' capable of measuring heart rate, respiration, body temperature and other physiological parameters could aid athletes in training and physical competition (Lymberis, 2005; Milenkovic et al., 2006). Emergencies and physical limits could be detected with precision.</p>

Table 1: Personal Health Monitoring technology examples

Table 2 – Sub-Categories of PHM

Category of PHM	Description	References
Mobile Monitors (n = 24)	Devices and sensors carried, worn by, or implanted in the user.	(Agrafioti et al., 2011; Brey, 2005; De Bleser et al., 2011; Demiris et al., 2009; Dorsten et al., 2009; Fellbaum, 2008; Friedewald et al., 2007; Gammon et al., 2009; Gaul and Ziefle, 2009; Kosta et al., 2010; Kovach et al., 2011; Landau et al., 2010a, 2010b; Lauriks et al., 2007; Melander-Wikman et al., 2007; Mittelstadt et al., 2011; Monahan and Wall, 2007; Nordgren, 2012; Pentland, 2009; Rigby, 2007; Robinson et al., 2007; Welsh et al., 2003; Ziefle and Röcker, 2010, 2010)
Environmental Monitors (n = 46)	Devices and sensors embedded in an environment, such as a home, vehicle, or workplace, or a stationary medical appliance.	(Agree et al., 2005; Bowes et al., 2011; Brey, 2005; Chan et al., 2008; Coughlin et al., 2007; Courtney, 2008; Courtney et al., 2008, 2007; Demiris and B. Hensel, 2009; Demiris et al., 2008, 2004; Demiris, 2009; Ding et al., 2011; Dorsten et al., 2009; Essén, 2008; Fellbaum, 2008; Friedewald et al., 2007; Fugger et al., 2007; Gentry, 2009; Kenner, 2008; Lauriks et al., 2007; Lyon, 2001; Mahoney et al., 2007; Martin et al., 2007; McLean, 2011; Melenhorst et al., 2004; Mittelstadt et al., 2011; Neild et al., 2004; Niemeijer et al., 2011, 2010, 2010; Nordgren, 2012; Palm, 2011; Remmers, 2010; A. S. Rigaud et al., 2011; Rigby, 2007; Sadri, 2011; Stowe and Harding, 2010; Tiwari et al., 2010; Townsend et al., 2011; van Hoof et al., 2011, 2007; Vuokko, 2008; Welsh et al., 2003; Y.-H. Wu et al., 2012; Ziefle and Röcker, 2010; Zwijsen et al., 2011)
Other/Ambiguous (n = 4)	Generic PHM technologies or	(B. K. Hensel et al., 2006; Kaplan and

	artefacts identified (e.g. telecare), but not specific applications.	Litewka, 2008; Percival and Hanson, 2006)
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Table 3 – Demographics of Target Users

Demographic		References
Elderly (n = 51)	Target audience described as 'elderly' or 'older'.	(Agree et al., 2005; Bowes et al., 2011; Chan et al., 2008; Coughlin et al., 2007; Courtney, 2008; Courtney et al., 2008, 2007; Demir and B. Hensel, 2009; Demir et al., 2009, 2008, 2004; Demir, 2009; Ding et al., 2011; Dorsten et al., 2009; Essén, 2008; Fellbaum, 2008; Friedewald et al., 2007; Fugger et al., 2007; Gaul and Ziefle, 2009; Gentry, 2009; B. K. Hensel et al., 2006; Kenner, 2008; Landau et al., 2010a, 2010b; Lauriks et al., 2007; Mahoney et al., 2007; Martin et al., 2007; McLean, 2011; Melander-Wikman et al., 2007; Melenhorst et al., 2004; Mittelstadt et al., 2011; Neild et al., 2004; Niemeijer et al., 2011, 2010; Nordgren, 2012; Palm, 2011; Percival and Hanson, 2006; Remmers, 2010; A. S. Rigaud et al., 2011; Robinson et al., 2007; Sadri, 2011; Steele et al., 2009; Stowe and Harding, 2010; Tiwari et al., 2010; Townsend et al., 2011; van Hoof et al., 2011, 2007; Welsh et al., 2003; Y.-H. Wu et al., 2012; Ziefle and Röcker, 2010; Zwijsen et al., 2011)
Ambiguous Age (n = 11)	Target audience age not described.	(Agrafiotti et al., 2011; De Bleser et al., 2011; Fellbaum, 2008; Friedewald et al., 2007; Kaplan and Litewka, 2008; Kosta et al., 2010; Mittelstadt et al., 2011; Monahan and Wall, 2007; Niemeijer et al., 2010; Nordgren, 2012; Pentland, 2009)
Chronic Patients (n = 17)	Target audience with a chronic illness such as dementia or diabetes requiring long-term care.	(Fellbaum, 2008; Friedewald et al., 2007; Gentry, 2009; Kenner, 2008; Landau et al., 2010a, 2010b; Lauriks et al., 2007; Mahoney et al., 2007;

		Martin et al., 2007; Mittelstadt et al., 2011; Niemeijer et al., 2011; Nordgren, 2012; A. S. Rigaud et al., 2011; Robinson et al., 2007; van Hoof et al., 2007; Welsh et al., 2003)
Acute Patients (n = 12)	Target audience with an acute health condition.	(Agrafiotti et al., 2011; De Bleser et al., 2011; Fellbaum, 2008; Friedewald et al., 2007; Kosta et al., 2010; Kovach et al., 2011; Mittelstadt et al., 2011; Monahan and Wall, 2007; Niemeijer et al., 2010; Nordgren, 2012; Pentland, 2009; Rigby, 2007)
Healthy (n = 3)	Target audience not described in terms of health status, such as in informational or preventative PHM applications (e.g. lifestyle monitors).	(Monahan and Wall, 2007; Niemeijer et al., 2010; Pentland, 2009)
Other (n = 1)	Field agents, e.g. military.	(Agrafiotti et al., 2011)

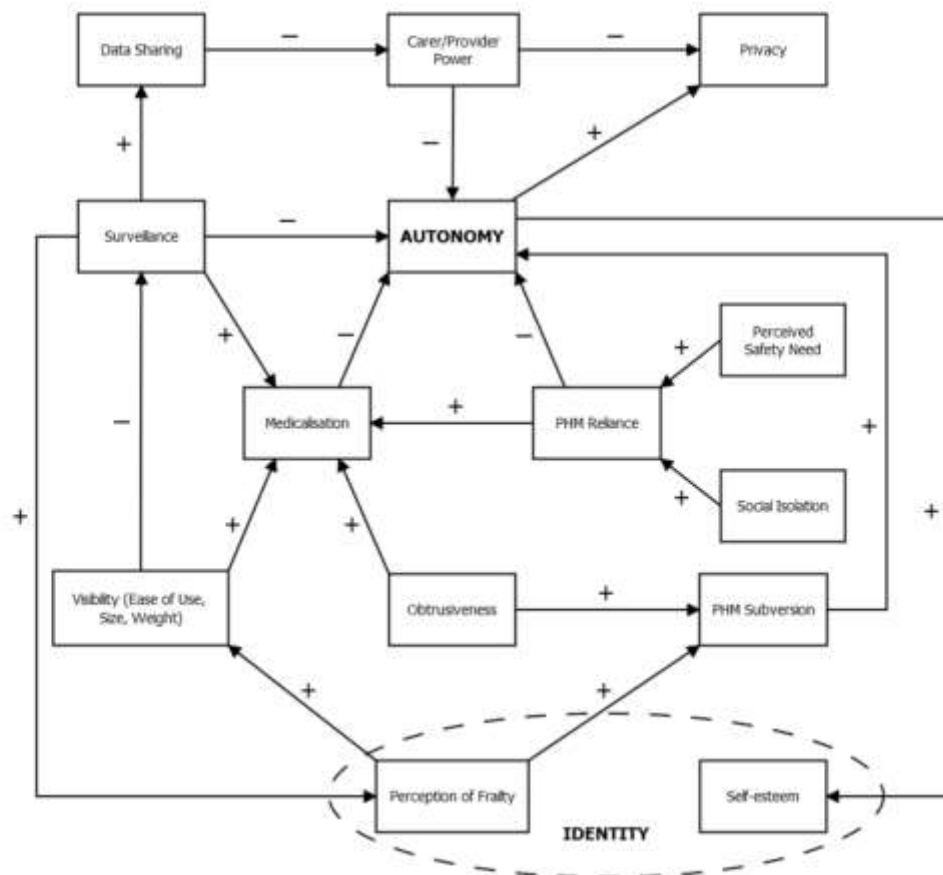
Table 4 – Ethical Themes

Theme	Central Issues and Concepts	References
Privacy (n = 38)	Data privacy, personal privacy, security as privacy-enabling	(Agrafioti et al., 2011; Bohn et al., 2005; Bowes et al., 2011; Brey, 2005; Chan et al., 2008; Coughlin et al., 2007; Courtney, 2008; Courtney et al., 2008; Demiris and B. Hensel, 2009; Demiris et al., 2009, 2004; Demiris, 2009; Ding et al., 2011; Dorsten et al., 2009; Essén, 2008; Friedewald et al., 2007; Gaul and Ziefle, 2009; Kosta et al., 2010; Kovach et al., 2011; Landau et al., 2010a; McLean, 2011; Melenhorst et al., 2004; Mittelstadt et al., 2011; Neild et al., 2004; Niemeijer et al., 2010; Pentland, 2009; Percival and Hanson, 2006; Remmers, 2010; Rigby, 2007; Sadri, 2011; Steele et al., 2009; Stowe and Harding, 2010; Tiwari et al., 2010; Townsend et al., 2011; van Hoof et al., 2011, 2007; Welsh et al., 2003; Zwijsen et al., 2011)
Autonomy (n = 30)	Rights to freedom, independence, personal decisions, technological dependence	(Bowes et al., 2011; Brey, 2005; Demiris and B. Hensel, 2009; Demiris, 2009; Dorsten et al., 2009; Essén, 2008; Friedewald et al., 2007; Fugger et al., 2007; Gaul and Ziefle, 2009; Gentry, 2009; Kenner, 2008; Kosta et al., 2010; Landau et al., 2010a, 2010b; Martin et al., 2007; Mittelstadt et al., 2011; Monahan and Wall, 2007; Niemeijer et al., 2011, 2010; Percival and Hanson, 2006; Remmers, 2010; Rigby, 2007; Robinson et al., 2007; Steele et al., 2009; Stowe and Harding, 2010; Tiwari et al., 2010; Townsend et al., 2011; van Hoof et al., 2007; Welsh et al., 2003; Zwijsen et al., 2011)
Obtrusiveness & Visibility (n = 23)	Physical/psychological prominence, subversion, public visibility, psychological disappearance, covert monitoring,	(Bowes et al., 2011; Brey, 2005; Courtney, 2008; Courtney et al., 2007; De Bleser et al., 2011; Demiris and B.

	inadvertent monitoring, context-specific	Hensel, 2009; Demiris, 2009; Demiris et al., 2008, 2004; Essén, 2008; Fellbaum, 2008; B. K. Hensel et al., 2006; Kaplan and Litewka, 2008; Kenner, 2008; Landau et al., 2010b; Melenhorst et al., 2004; Mittelstadt et al., 2011; Neild et al., 2004; Robinson et al., 2007; Tiwari et al., 2010; Townsend et al., 2011; van Hoof et al., 2011; Zwijsen et al., 2011)
Stigma & Identity (n = 16)	Public/private stigma, self-esteem, group identification, aesthetics, community implementation, risk-taking, behavioural expectations, passive control	(Bowes et al., 2011; Coughlin et al., 2007; Courtney, 2008; Ding et al., 2011; Essén, 2008; Gaul and Ziefle, 2009; McLean, 2011; Mittelstadt et al., 2011; Niemeijer et al., 2010; Percival and Hanson, 2006; Remmers, 2010; Steele et al., 2009; Tiwari et al., 2010; van Hoof et al., 2011; Y.-H. Wu et al., 2012; Zwijsen et al., 2011)
Medicalisation (n = 9)	Altered perceptions of home, health obsession, overdiagnosis, doctor-patient relationship	(Bowes et al., 2011; Chan et al., 2008; Courtney et al., 2008; Demiris and B. Hensel, 2009; Gentry, 2009; Mittelstadt et al., 2011; Niemeijer et al., 2010; Zwijsen et al., 2011)
Social Isolation (n = 21)	Replacement of human care, supplementary care, lack of social interaction, social networking, informal carer burdens	(Agree et al., 2005; Bowes et al., 2011; Chan et al., 2008; Demiris, 2009; Demiris et al., 2004; Friedewald et al., 2007; Gentry, 2009; Kaplan and Litewka, 2008; McLean, 2011; Mittelstadt et al., 2011; Niemeijer et al., 2010; Nordgren, 2012; Palm, 2011; Pentland, 2009; Percival and Hanson, 2006; Sadri, 2011; Stowe and Harding, 2010; Tiwari et al., 2010; van Hoof et al., 2011; Y.-H. Wu et al., 2012; Zwijsen et al., 2011)
Delivery of Care (n = 9)	Care community surveillance, carer-patient power relationships, behaviour monitoring, information overload, job security, workplace surveillance	(Kaplan and Litewka, 2008; Kenner, 2008; Mittelstadt et al., 2011; Monahan and Wall, 2007; Niemeijer et al., 2010; Percival and Hanson, 2006; Remmers, 2010; Tiwari et al., 2010; Vuokko, 2008)
Safety &	Misdiagnosis, priority of carer beliefs, internal	(Courtney, 2008; Courtney et al., 2008;

Technological Need (n = 12)	vs. external perceptions of need, developer claims, PHM enhancing health and well-being,	Ding et al., 2011; Dorsten et al., 2009; Gammon et al., 2009; Kaplan and Litewka, 2008; Landau et al., 2010a, 2010b; Lauriks et al., 2007; Neild et al., 2004; Niemeijer et al., 2011; Tiwari et al., 2010)
Other (n = 22)	Informed consent, data mining, equity of access, social surveillance, behavioural monitoring, white lies	<p>Informed Consent: (Bagūés et al., 2007; Bowes et al., 2011; Chan et al., 2009; Demiris and B. Hensel, 2009; Demiris et al., 2009; Gammon et al., 2009; Kaplan and Litewka, 2008; Kenner, 2008; Martin et al., 2007; Mittelstadt et al., 2011; Neild et al., 2004; Remmers, 2010; Stowe and Harding, 2010)</p> <p>Data Mining: (Bowes et al., 2011; Fellbaum, 2008; Pentland, 2009; Remmers, 2010)</p> <p>Equity of Access: (Demiris, 2009; Kosta et al., 2010)</p> <p>Social Surveillance: (Friedewald et al., 2007; Mahoney et al., 2007; Monahan and Fisher, 2010; Monahan and Wall, 2007; Pentland, 2009; Remmers, 2010)</p> <p>Behavioural Monitoring: (Fellbaum, 2008)</p> <p>White Lies: (Fellbaum, 2008)</p>

Figure 1: Cognitive Map of Linkages between Ethical Themes



How to Shape a Better Future?

On the Epistemic Value of Empirical Research on the Ethics of Emerging Technologies

Abstract

Empirical research into the ethics of emerging technologies, often involving foresight studies, technology assessment or application of the precautionary principle, raises significant epistemological challenges by failing to explain the relative epistemic value of contentious normative claims about future states. This weakness means that it is unclear why the conclusions reached by these approaches should be considered valid. This paper responds to this problem by developing a conceptual framework to understand the epistemic value of uncertain normative claims. To better understand the nature of the problem, the relationship between norms, facts and the future is explored in light of potential meta-ethical fallacies faced in the field of empirical ethics. Weaknesses of current approaches are then explored. We argue that the epistemic value of uncertain normative claims can be understood within Habermas' approach to political discourse, which requires 'translation' of uncertain claims to be comprehensible to other stakeholders in discourse. Translation thus provides a conceptual framework to understand the difficulties of evaluating the validity of uncertain normative claims, which requires methodological innovation to overcome current epistemic uncertainty. The paper contributes a coherent epistemological framework which can be adopted by the aforementioned approaches to research supporting anticipatory evidence-based policy, governance and system design.

Keywords

emerging technologies, empirical ethics, evidence-based policy, technology assessment, epistemology

Introduction

It has long been established that technologies can cause ethical problems (Dusek 2006). There is broad agreement that an early recognition of these issues may provide avenues to address them through anticipatory policy and regulation. A core issue is that a tension exists between the empirical and the normative dimension of dealing with future and emerging technologies. This is the heart of the Collingridge (1980) dilemma which states that it is impossible to know the consequences of an emerging technology at an early stage when it would be comparatively simple to change the technology's trajectory. Once the technology is more established and it becomes clearer what its social and ethical consequences are going to be, it becomes increasingly difficult to affect its outcomes and social context. Despite the fundamental problems posed by the Collingridge dilemma, there continue to be attempts to better understand future technologies and to predict the ethical issues they are likely to raise with a view to addressing them early through anticipatory policy and regulation.

There exists a rich history of attempts to develop epistemologically robust ways of understanding how emerging technologies will affect the future, for example in future studies or technology foresight (Cuhls 2003; Georghiu 2008). Such approaches often attempt to provide an empirical basis for policy makers due to a growing demand for evidence-based policy (Banks 2009). Despite this rich field of research, there is still no agreement on some of the conceptual underpinnings and the question of how our understanding of possible futures can or should be translated into practical activities that will allow for the desirable shaping of future technologies.

At the heart of the conceptual disagreement is a common epistemological problem: predictions and anticipatory action are based on normative evidence with unclear epistemic value. We suggest in this paper that, despite all the conceptual problems that can be raised by research aiming to provide action-oriented advice to policy and decision makers, researchers *can* base reasonable validity claims on the normative empirical research on the ethics of emerging technologies *while uncertainty still prevails*. The solution we suggest is to treat future-oriented claims arising from empirical work in the same way as other contentious validity claims. Drawing on Habermas' recent works, we argue that uncertain normative claims about the future can be treated analogously to uncertain religious claims in political discourse. This allows the incorporation of uncertain future-related empirical research and statements on normative aspects in the broader discussion of emerging technologies and public policy.

On this conceptual basis we then present examples of two future-oriented research projects that look at normative aspects of emerging technologies. We show how the knowledge claims raised in these projects map onto the conceptual foundations developed earlier, suggesting ways forward in the development of a 'methodology of translation'. This leads to the conclusion which explains how normative empirical research can build on our conceptual ideas in order to play a more *prominent and appropriate* role in public discussions and policy advice.

Norms, Facts and Emerging Technologies

The core problem of this paper is the relationship between empirical research and anticipatory action with regards to future, emerging, and therefore uncertain technological developments. In order to clarify our contribution to understanding this relationship, a brief exploration into prior relevant discourses is required. What follows is a review of established positions on the relationship between facts and norms, description and prescription. This leads to a discussion of ethics under conditions of uncertainty which is followed by an analysis of current attempts to coherently incorporate normative empirical data into ethical analysis. Finally, a reconciliation of the epistemic difficulties of uncertainty with the need for anticipatory normative action is offered.

The Relationship of Facts and Norms

To be justifiable, anticipatory decisions require a legitimate source of morality, as determined by the relationship between current and ideal practice, or facts and norms. Conceptualising the appropriate interaction between facts and norms is a core problem of ethics and by no means novel. Moral philosophy has developed a plethora of approaches that aim to provide an unambiguous source of morality. Well known examples include the Kantian basis of normativity in reason (Kant 1827; 1870),

the utilitarian idea of deducing normativity from utility (Mill 2002) or the hope that normativity can reliably be derived from intuition or sentiments (Smith 2007).

This paper does not offer the space to do this long and complex discussion any justice. The main reason for mentioning the problem of the source of morality is that it relates directly to the question of the relationship between normativity and empirical research. This is another well-established problem, aspects of which have been discussed under headings such as the "is-ought problem", "Hume's Guillotine" and the "naturalistic fallacy."

The core of this discussion goes back to Hume's (2004) view that 'ought' cannot be deduced directly from 'is', that prescription needs to be independent of description. Moore (Moore 1993) asserted a similar position, saying that "good" cannot be defined and any attempt to do so commits the fallacy by substituting other properties of something that is good for defining the good. These arguments rely upon a fundamental conceptual distinction between 'is' and 'ought' which requires any normative conclusion to have a normative premise.

The distinction has been broadly upheld in empirical work on technology, for example in normative approaches such as value-sensitive design (Friedman, Kahn, and Borning 2008). At the same time, the conceptual segregation between 'is' and 'ought' has met with resistance. Magnani (2007) concurs with Searle (1964) that the intellectual tradition strictly distinguishing between 'is' and 'ought' is "bizarre." He argues that the truth of a statement implies a prescription to believe it. Similarly, Floridi (2010, 90) points to the tradition of classical thinkers from Plato to Spinoza who saw the roots of ethics in being. He then bases his own conception of information ethics on a moral worth of information which arises from its being. A further example of such a naturalist position that deduces 'ought' from 'is' was provided by Jonas's (1984) "principle responsibility" where he argues that there is a new categorical imperative that we must not risk human survival in light of the technical possibility of eradicating humanity. He postulates a sort of meta-responsibility which requires the possibility of responsibility by safeguarding human existence. A further figure of argument is that natural processes can inform our normative intuitions. We can, for example, learn about ourselves and by extension about our moral duties and obligations by observing the natural world and natural processes, such as evolution (Mumford 1996, 19). A final and important aspect of a naturalistic approach to 'is' and 'ought' is the reliance on religious figures of moral thought. Adherents of religion tend to deduce normative statements from their authoritative source and they are often related to beliefs about religious facts. The existence of a personal god may lead to the acceptance of normative prescriptions that emanate from this god. While this can easily be seen in many interpretations of Abrahamic religion, a similar merging of 'is' and 'ought' can be observed elsewhere (Hongladarom 2005).

The purpose of this brief elaboration was not to provide comprehensive coverage of the problem area (cf. Black 1964), but to set the scene for an exploration of the way in which moral philosophers, ethicists and social scientists work empirically, including their integration of description and prescription in ethical analysis.

Facts and Norms in Empirical Ethical Analysis

The conceptual distinction between description and prescription presents a practical problem for researchers intending to use empirical information describing “how the world is” to suggest “how the world should be.” However, an examination of the normative content of empirical data and its treatment in the last decade suggests that the importance of the problem may be overstated. Historically, empirical data has had a supportive yet detached relationship with ethics. Social scientists and ethicists often work separately on a single project, with the former responsible for gathering empirical data and the latter tasked with analysis and reaching normative conclusions (Molewijk et al. 2003, 71). This division of work itself stems from affirmation of the fact-value gap, according to which the descriptive world remains the domain of scientists, while the prescriptive world belongs to ethicists (Molewijk et al. 2003, 71). Under such a separation ethicists have been limited to using descriptive empirical data (1) to apply ethical theory in the context of a policy or action (Molewijk et al. 2003, 71; McMillan 2008, 17–8); (2) to assess the validity of assumptions upon which moral theories are based (De Vries and Gordijn 2009, 195; Leget, Borry, and De Vries 2009); (3) to gain insight into social practices for the identification of relevant cases and stakeholders in ethical deliberation (Van Hooren et al. 2008, 168). Each of these examples upholds the conceptual distinction between description and prescription.

In contrast to prior practice, the last decade has seen the emergence of iterative integration of empirical data in ethical analysis (Musschenga 2005, 468; De Vries and Gordijn 2009, 193). This movement, termed “empirical ethics,” has arisen from the recognition that empirical data can be usefully employed in ethical analysis to build and translate ethical theory into “middle-range principles”, refine ethically questionable practices and reach contextually-sensitive normative conclusions for practical purposes including policy guidance (Birnbacher 1999, 321; Musschenga 2005, 469; Leget, Borry, and De Vries 2009). Empirical ethics is best understood as a mentality guiding the use of empirical data in ethical analysis. Proponents are far from unified in terms of philosophical background and methodology, yet they tend to share three basic assumptions: (1) studying the moral beliefs of individuals in a practice yields meaningful normative empirical data that should be a starting point for ethics (Borry, Schotsmans, and Dierickx 2004; Baldwin 2008, 109; De Vries and Gordijn 2009, 193); (2) descriptive and normative approaches are inherently complementary; and (3) empirical ethics cannot rely on context alone for its determination of morality, but must incorporate both empirical data and ethical theory (Borry, Schotsmans, and Dierickx 2004; De Vries and Gordijn 2009, 193). Empirical ethicists therefore attribute value to the moral beliefs of individuals involved in a practice (or “moral practitioners”), because the practice provides them with unique “moral experiences” (Musschenga 2005). This attribution of value is coherent with (but not limited to) the ontological and epistemological commitments of philosophical positions involving discourse (i.e. discourse ethics, hermeneutics), which implicitly support normative empirical data as a legitimate source of morality and starting point for ethical analysis. Accordingly, empirical ethics affirms that valid normative empirical data can be collected, challenged and refined by engaging with the experiences of individuals involved in a practice. The distinction between description and prescription collapses in discourse with moral practitioners.

Debate over the conceptual separation of description and prescription will continue unabated, but it should not prevent further exploration of the epistemic value and treatment of normative empirical

data in ethical analysis. While empirical ethics has contributed to this debate within research into current practices, it has not yet turned its attention to the unique epistemic challenges presented by future practices and emerging technological developments. Evidence-based policy which responds to emerging technological challenges requires a legitimate source of morality for justification. Without an account of the epistemic value of uncertain normative claims, the validity of some of the evidence base for anticipatory policy cannot be established conclusively. This does not imply that uncertain normative claims cannot be included in policy discourse, but rather that we currently lack a complete set of criteria by which their validity can be established. To solve this problem, a new conceptualisation of the relationship between description and prescription, or facts and norms, under conditions of uncertainty is required.

Ethics, Uncertainty and Emerging Technologies

Before a reconciliation of facts, norms and the future can be offered, the challenges of uncertainty must be understood. These challenges are best explored through consideration of current approaches to the ethical assessment of emerging technologies, of which the Precautionary Principle (PP) and Technology Assessment (TA) are perhaps the best known. In understanding the challenges, it is important to note the difference between uncertainty and risk, although both concepts are related. With uncertainty the probabilities of possible outcomes are unknown, whereas with risk "the probability distribution ... is known or predictable" (Ahmed and Skogh, 2006, 183). In looking at technologies still under development, researchers are often faced with uncertainties for which even the minimal data required for the maths of imprecise probability is unavailable. With this said, the paradigmatic case considered here is a technology that is sufficiently developed for meaningful discourse to be possible about the nature of the technology and its initial uses, but where there is still uncertainty about its future implications. Under this type of uncertainty of future technologies, one can ask on which grounds decisions and policies can be made and justified.

In considering the challenges of uncertainty we are attempting to map the epistemic value of 'uncertain normative claims'. In the context of ethical assessment of emerging technologies, uncertain normative claims are contentious arguments which describe the appropriate response to future social and ethical impacts of emerging technologies, or what 'should' be done in the future. Normativity refers to any declaration with prescriptive or evaluative content, including statements of moral evaluation (such as "this technology is good") or prescription (such as "one should do ..."). As the future is inherently uncertain, the claims are not epistemologically equivalent with claims based upon existing social practices (cf. Widdershoven, Abma, and Molewijk 2009) or empirically observable phenomena (cf. Popper 1959).¹ If uncertain normative claims are to be employed in future-oriented ethical assessment, an alternative account of their epistemic value is required which acknowledges the inherent uncertainty of the future.

¹ How validity derives from scientific observation is contentious question. We adopt Popper's critical rationalist position, in which all scientific knowledge is provisional and held up to the standard of falsification. Certainty, then, refers to the falsifiability of a scientific hypothesis or theory.

Evidence-based Decisions under Conditions of Uncertainty

In the past, the difficulties of predicting the future (uncertainty) have been addressed through the creation of decision rules, which guide decision making in absence of reliable empirical or statistical data regarding (for example) risks and impacts. A notable early decision rule was the 'rule of insufficient reason' (Laplace rule) otherwise known as the 'principle of indifference' – that when we are too unsure about the probability of possible outcomes "we should treat them as if they were equally likely" (Goodin 1983, 165–6; Sinn 1980). This has been shown to be inappropriate in very many circumstances; subsequent research has advanced on decision rules at varying levels of uncertainty in a number of ways, resulting in a "vast literature" (Ahmed and Skogh 2006, 184) including, for example the "diversification theorem", which explains why it may be wise to spread investments over a number of assets when the returns are uncertain.

The uptake in research reflects the on-going debate about decision rules under conditions of uncertainty, largely provoked by debates about policies for new technologies, and especially environmental policies during the late 20th and early 21st centuries. Against this background the question of how to assign epistemic value to uncertain normative claims becomes urgent. Opponents of regulation have time and again argued for a position that has been characterised (Wagner 2003, 77 n.60) as saying that regulation should not occur because there is "not enough science to justify protective regulation."

In response proponents of regulation no longer rely entirely on trying to provide scientific proof that will satisfy their opponents. Sometimes this is because "standards for the requisite evidence are never articulated" (Wagner 2003, 77 n.60) and – thus – never met to the satisfaction of opponents of regulation. Even without scepticism towards the tactics of opponents of regulation, proponents may have realised that requiring scientific proof of harmful relationships to justify regulation is inappropriate. There are two fundamental reasons for this. The first is the epistemic status of science: scientific theories are, fundamentally, provisional (awaiting falsification) (Popper 1959), so conclusive evidence to justify regulation would forever remain out of reach. The second is because of the conservatism of science: in identifying relationships science does not work on the basis of balance of probabilities, but rather seeks to "minimise 'false positives'", even though in doing so its "procedures increase the chance of 'false negatives', that is, failing to assert that there is a relationship when there is a relationship" (John 2010, 5).

Rather than always seeking to provide scientific proof that will satisfy opponents, proponents of environmental regulation have looked for arguments that regulation should begin before there is certainty about the harmful effects of the processes they want regulated; in other words, they seek decisions under conditions of uncertainty.

The Precautionary Principle

Taking a leading position among these arguments is the Precautionary Principle (PP), which came to global prominence with the Rio Declaration of 1992 (UNCED 1992). Although a common definition is lacking (Gardiner 2006, 34–5), the core content of the PP is found in the Wingspread Statement (1998) about environmental impacts of human activity:

"When an activity raises threats of harm to human health or the environment, precautionary measures should be taken even if some cause and effect relationships are not fully established scientifically."

From its creation the PP has had a severely (but justifiably) poor philosophical reputation (Gardiner 2006, 33; Hughes 2006, 448–9, 463), although recent adaptations have sought to improve its standing. The principle's reputation comes largely from the "paradox of precaution" (a term apparently coined, but not philosophically analysed, by (Morris 2000) – the term "paradox" had previously been applied to the precautionary principle in a different way by (Freestone 1991). The "paradox of precaution" arises if the precautionary principle is interpreted as saying that we must avoid harm by eschewing risky, but potentially beneficial technologies. Under this interpretation harm arises since the benefits of adopting the technologies are foregone with "for example... lost opportunities to prevent disease and death", resulting in a "precautionary principle [that] would instruct us to refrain from implementing itself" (Hughes 2006, 449). Beyond this, even enthusiastic advocates have been willing to accept it is "ill-defined and imperfectly translatable into codes of conduct" (Jordan and O'Riordan 1999, 15).

Work since 2006 (cf. Gardiner 2006; Hourdequin 2007; John 2010), however, has produced more philosophically robust formulations, which may give valuable guides to action in certain circumstances. Gardiner's (2006, 47–8) work turns on criteria for the employment of the PP. A key insight from Gardiner is that the PP applies in conditions of uncertainty, but not when ignorance exists of the range of outcomes over which there is probabilistic uncertainty.

Unfortunately, the PP lacks a mechanism for identifying and normatively assessing potential outcomes. Such an "identification mechanism," guided perhaps by normative empirical research, would help identify possible outcomes under conditions of uncertainty. Approaches to the ethical assessment of emerging technologies require such a mechanism which involves cross-referencing "descriptions of the technology...with ethical values and principles" (Brey 2011). Identification mechanisms therefore not only identify a list of possible ethical outcomes, but give normative content to these outcomes by locating them within existing ethical theories and concepts. The interplay between facts and norms can be said to exist in this process. Therefore, without such a mechanism, the PP is of little use in evidence-based policy making, and does not explore the relationship between facts and norms in future-oriented ethical assessment.

Technology Assessment

Descriptive and prescriptive information relating to the potential outcomes of emerging technologies is required to use the PP in decision-making. Such information can be gathered in empirical ethics research, in which normative claims are made about emerging technologies. Of the approaches capable of collecting, analysing and applying such information under conditions of uncertainty, Technology Assessment (TA) is perhaps the most widely used. TA is a field which studies and evaluates the interaction between new technologies and the environment, industry and society (Tran and Daim 2008). Similarities are found with other plausible approaches for responding to emerging technologies including participative design (Mumford 2003), value-sensitive design (Friedman, Kahn, and Borning 2008) and other socio-technical approaches (Sandberg 1985). Studies engaging in TA often work on

“known or potential applications” of emerging technologies as well as future and technological forecasting studies (Brey 2011; Cagnin et al. 2008; Georghiu 2008). Crucially, TA includes an “identification mechanism,” a normative interest in future technologies, and a range of empirical methods to pursue this interest.

The field emerged in response to experiences of undesirable or unintentional side effects of emerging technologies (Grunwald 2009). TA comprises a family of approaches that aim to combine empirical research on likely consequences of technologies with normative insights. Its various flavours, including participative TA (Joss and Bellucci 2002; van Eijndhoven and van Est 2002) and constructive TA (Genus and Coles 2005), employ a broad array of methods which include participation from a variety of stakeholders, most notably laypersons as representatives of future users of the technologies in question.

By anticipating and responding to the challenges presented by emerging technologies during the development and early deployment cycles, TA studies aim to guide the development and regulation of technology in more desirable directions (Brey 2011). Grunwald (2009) identifies four challenges which TA responds to:

“that of integrating at an early stage in decision-making processes any available knowledge on the side effects, that of supporting the evaluation of the value of technologies and their impact, that of elaborating strategies to deal with the knowledge uncertainties that inevitably arise, and that of contributing to the constructive solving of societal conflicts on technology and problems concerning technological legitimisation.”

TA is therefore united as a field by its emphasis on the production and evaluation of knowledge concerning social, economic and environmental impacts for the purpose of providing recommendations to steer the social response to emerging technologies.

Problems of Normative Evaluation in TA and PP

TA studies often refer to the Precautionary Principle in making recommendations for social response to the uncertainties of emerging technologies (Grunwald 2009, 1108). This situation creates a problem for TA as most versions of the PP lack guidance on how to balance competing uncertain normative claims. The reliance on the PP may be a conscious decision—the social response must surely be sensitive to the context in which the technology will be used, which will influence the relative value of normative claims. Still, accepting this limitation of the PP ignores a common problem of any approach to the assessment of future technologies. Even if normative assessments give importance to context (which we believe they should), there must be criteria by which the relative value of (uncertain) normative claims are determined. While these criteria may change according to context, culture, religion, ethical viewpoint etc., the need for an evaluative mechanism does not go away. Balancing competing claims without knowledge of their epistemic value is akin to judging the scientific merit of a controlled trial without an understanding of how controls contribute to the scientific method—the key piece of knowledge for determining the value of uncertain normative claims, their epistemic status, is missing.

The Importance of Epistemology in Anticipatory Decision-Making

We are now at the point where we can return to the original problem discussed in this paper. Emerging technologies can raise ethical issues that policy makers would like to address proactively. Being situated in the future gives such technologies uncertain outcomes. Despite this, empirical research is still conducted to determine their possible normative outcomes. However, as a result of the uncertainty of the future, such normative empirical research requires a different type of truth claim compared with objectivist research in the natural sciences, which bases truth claims validity measured in terms of falsifiability (Popper 1959). While decision principles such as PP can give some indication of appropriate evaluative mechanisms, these only take effect once stakeholders in decision-making agree upon a shared view of facts and norms. TA and related approaches set out to provide empirical input into such policy development and decision mechanisms. However, the question of the epistemological evaluation of the outcomes of TA research remains open, which precludes a shared foundation of facts and norms on which normative evaluation may occur. How can a decision maker who aims to make evidence-based policy interpret the validity of empirical normative claims about emerging technologies? We suggest in the following section that this can be done by requiring the translation of such empirical work on the basis of Habermas' Discourse Ethics.

A Reconciliation of Norms, Facts and the Future: Discourse Ethics and the Interpretation of Uncertain Validity Claims

The relationship between 'is' and 'ought', the way in which empirical ethics deals with this relationship, and the broader context of ethics under conditions of empirical uncertainty have been considered thus far. The purpose of considering these topics is to develop a sound theoretical basis that can be used to reconcile empirical research and normative aspects of future and uncertain technical developments. For this purpose we now need to show that the different aspects under consideration can be combined in a theoretically satisfactory manner to provide a coherent account of the epistemic value of normative empirical claims under conditions of uncertainty. There are, no doubt, numerous ways of providing such theoretically sound conceptual foundations. We argue that, in terms of epistemic value, uncertain statements concerning normative aspects of emerging technologies can be treated analogous to religious statements which, according to Habermas (2008; 2011), should be treated as valid and legitimate interventions in public discourses. This is not to say that uncertain normative claims and religious statements share similar foundations (e.g. faith, superstition), but rather that both possess inherent uncertainty which must affect how they are treated in discourse.²

One appropriate way of achieving the aim of providing the necessary theoretical underpinnings for normative research on emerging technologies is to make use of the existing body of work on discourse ethics. The rationale for this choice is that discourse ethics is a well-established ethical approach that deals with the relationship between normative and empirical statements. Discourse ethics furthermore has an established track record of being applied to (human interaction with) technology (Mingers and

² Certainty refers here to the possibility of falsification of the claim and its evidence base. Uncertain normative claims are characterised by reliance upon descriptions of the future which are inherently uncertain, whereas religious claims rely upon faith or belief beyond empirically observable phenomena.

Walsham 2010). Finally, recent developments in the broader political discourse theory as put forward by Habermas allow for the incorporation of statements that lack the epistemological certainty that can be expected in statements about empirical observations of existing phenomena. In order to develop this position, discourse theory and discourse ethics must be briefly introduced to demonstrate their usefulness with regards to scientific and technical developments. It must be shown how uncertain normative claims can be accommodated in discourse.

Discourse Ethics

The term "discourse ethics" was originally coined by Karl-Otto Apel and was adopted and developed by Jürgen Habermas. Space limitations preclude a detailed and in-depth discussion of discourse ethics; however, a brief overview is provided which will allow us to demonstrate that discourse ethics provides a theoretical foundation of the problem addressed this paper. For the purposes of this argument we will concentrate on the Habermasian version of discourse ethics. Discourse ethics must be understood in the broader context of Habermas' theory of communicative action (TCA) (1981). According to the TCA human beings as social entities need to communicate in order to survive and prosper. Humans have a range of possibilities of communicating, with communicative action being the best or most highly developed. Whenever human beings communicate, a set of validity claims arise: truth (Wahrheit), rightness (Richtigkeit) and authenticity (Wahrhaftigkeit). Communicative action requires the speaker to engage in a discourse whenever any of these validity claims are queried. This implies a willingness to engage with the interlocutor, to take her seriously and to be willing to change one's positions in the light of that argument (Habermas 1992). This brief basis of the TCA is important for the current paper because it indicates that **there is no fundamental distinction between normative and descriptive statements**. Any statement can raise validity claims relating to truth, normative rightness and the speaker's authenticity. All validity claims are subject to discursive questioning.

Habermas' discourse ethics incorporates these principles of the TCA and uses them to develop an explicit ethical theory (Habermas 1983; 1991). Discourse ethics is expressed in two basic principles, the discourse principle and the universality principle. The discourse principle states that only those norms can claim to be valid that meet (or could meet) with the approval of all affected in their capacity as participants in a practical discourse. The universality principle goes beyond the acceptability by the affected and states that the consequences and side effects arising from the general adherence of a norm have to be acceptable for all involved stakeholders and, ideally, for everybody.

Discourse ethics can be seen as a successor of Kantian deontology that incorporates the Kantian principle of universalizability and overcomes the limitations of the categorical imperative which is aimed at the individual. It is important to understand that discourse ethics is one aspect of a larger theoretical edifice and needs to be interpreted in this context. Habermas' work covers political and legal theory which are inextricably linked with ethical questions (Habermas 1996). It is therefore not surprising that applications of Habermasian thought can be found in areas where technology is used for purposes of communication in the public sphere (Heng and De Moor 2003; Lyytinen and Hirschheim 1988). While much work using Habermasian ideas uses his earlier and more sociological writings (Klein and Huynh 2004), it is important to note that recently Mingers and Walsham (2010) have made a convincing

argument that discourse ethics proper has the potential to help us understand normative aspects of technology.

Discourse ethics can thus be argued to overcome the limitations of the 'is-ought problem' and provides a theoretical position that allows empirical ethics research. **The discourse and universality principles provide criteria for evaluating norms which allow for normative as well as empirical interventions.** It requires practical discourses which allow the voicing of empirical observations as well as ethical positions.

Uncertain Normative Claims in Discourse

This leaves the final aspect at the core of this paper, namely the problem of uncertain normative claims. According to the TCA any validity claim can be queried and then needs to be defended using good arguments in a discourse. This raises the question of how to evaluate and defend statements about the future that are fundamentally uncertain.

Within the framework of discourse ethics and the TCA at least two strategies will be possible. One can use a methodological argument that defends statements with reference to the methodologies that were employed in arriving at the statements. A statement about an expected social or ethical consequence arising from an emerging technology could thus be defended by explaining the methodological approach that led to it. This is a rational way of dealing with the uncertainty of the future but it has the disadvantage that it can turn discourses about the ethical aspects of emerging technologies into discourses on future-oriented research methodology.

We believe that recent work by Habermas points to a better way of incorporating uncertain normative claims into ethical-political discourses and anticipatory decision-making. This goal can be accomplished by treating uncertain normative claims as analogous to religious beliefs. The relationship between the two is that they both occupy similar epistemological territory. Both types of claims rely upon or describe states of existence that are logically unknowable—metaphysics for the former, the future for the latter. As a result, neither can be falsified or tested through scientific means.

Habermas has discussed the role of religion in political discourse in some depth since the beginning of the current millennium (Habermas 2008; 2011). This focus was the result of the continuing prevalence of religious interventions in political discourses and the recognition that these interventions must be taken seriously because they can be strong motivators of political action and the basis of legitimate democratic positions. Habermas' question is how a post-metaphysical state, i.e. a state that is not based on religious convictions or traditions, can react to and incorporate religious positions. He argues that such a post-metaphysical state needs to be secular and neutral towards religious convictions, in order to facilitate the peaceful co-existence of different, possibly contradictory religious positions. Religious citizens in a secular state have a 'duty to translate' their religious claims into a secular or rational form if they expect their claims to be considered in discourse. At the same time, non-religious citizens have the duty to accept that religious positions can have a rational basis which may be valid in discourse, and have a right to be heard. There is thus the possibility of a discourse despite the fact that some interlocutors do not share the basic premises of the interventions of others. One can interpret this view

as the implementation of the principles of the TCA in cases of principled disagreement on the validity claims in statements.

This principle can be extended to cover uncertain normative claims arising from empirical work on future technologies. Such statements do not have the same epistemological status as statements about empirically observable phenomena. At the same time, they carry meaning and may fruitfully contribute to ethical-political discourses that shape the development of such technologies. What is required from the different interlocutors is (a) the ability and willingness to translate these uncertain normative claims into practically relevant statements and (b) the willingness by interlocutors who doubt the validity of such claims to listen to the translation in the attempt to use discourse to come to a better shared view of the social reality in which the discourse participants find themselves.

Translation of Uncertain Claims

The process of translation involves the reconstruction of unsupported and (perhaps) unjustified moral beliefs about future states into legitimate ethical claims. Moral beliefs about future states are vulnerable to propaganda, misinterpretation of evidence and ignorance. Accordingly, it would be foolish to apply a kind of Laplace rule and view all moral beliefs as equally valid without further analysis. We suggest that two steps are necessary to translate such beliefs into legitimate ethical claims that can be subjected to discourse. First, the justificatory evidence base upon which uncertain normative claims are constructed must be understood so transformational experiences, flaws in reasoning or false statements can be identified (and perhaps engaged in discourse). Second, the “normative truth content” of uncertain normative claims must be understood. To unpack this concept, it is helpful to review Habermas’ position on the utility of religious beliefs within a secular political society. Much as religious beliefs may rely upon adherence to questionable comprehensive doctrines, moral beliefs may be founded upon indefensible or subjective premises. However, both types of beliefs may contain legitimate conclusions or ‘normative truths’, albeit by reliance on questionable foundations. The process of translation thus identifies the normative truth of questionable beliefs and translates it into a defensible claim by (in the case of religious beliefs) translating it into secular terms or (in the case of moral beliefs) relating it to ethical concepts and theory. This allows the different interlocutors to agree or disagree on the content of the claims on the basis of mutual understanding.

Conceived as such, the purpose of translation is not to convince other stakeholders of the validity of an uncertain claim, but rather to reveal the foundation or ‘meaning’ of the claim for further discourse. Translation is meant to discard the metaphysical or uncertain elements of a claim which are incomprehensible to other stakeholders in a discourse. In practice, this requires converting the claim into terms or a frame of reference understood by or shared with the other stakeholders; for instance, translating religious claims between the metaphysical frameworks of different religions, or into purely secular terms for other citizens in a secular society. For uncertain normative claims about the future, translation may require identifying the principles or prescriptive claims which have been applied to the future context, or the characteristics of a future context which give ‘weight’ to the uncertain claim. The translation of statements from one context to another is thus the key to considering uncertain normative claims about emerging technologies as valid in evidence-based policy making. This raises a number of follow-on questions, such as: What constitutes a successful translation? Who needs to

translate what and to which degree? Are translations reversible? How can a discourse deal with competing translations? The approach we suggest here thus requires the development of a theory or 'methodology of translation' with relevant evaluative criteria (perhaps based in the TCA).

Translation in the Ethical Assessment of Emerging Technologies

At present, a 'methodology of translation' does not exist. It is not our aim here to develop such a methodology, but rather to show that Habermasian translation is an appropriate conceptual framework to comprehend the epistemic difficulties of incorporating uncertain normative claims into anticipatory evidence-based policy and the ethical evaluation of emerging technologies. If our account is successful, it follows that such discourses may be evaluated in terms of the translation of uncertain normative claims, requiring future development of a translation methodology, which goes beyond the scope of this paper. In lieu of a full theory, we briefly discuss two examples from current normative research into policy relevant interventions to demonstrate the development and application of our approach in practice. As they occurred, neither project had a concept of translation, or evaluative criteria to judge the success of translation; rather, the projects are reviewed to demonstrate how translation can be applied as a conceptual framework to attempts to ethically evaluate emerging technologies under conditions of uncertainty. Additionally, the principles and methodologies of the projects are sketched to suggest possible ways forward in the development of a practically useful methodology of translation.

ETICA

The ETICA project (Ethical Issues of Emerging ICT Application, <http://www.etica-project.eu>) was an EU research project funded by the Science in Society programme of the EU's 7th Framework Programme (GA no. 2301318) and ran from April 2009 to May 2011. The aim of the project, which could be characterised as a technology foresight project, was to identify emerging information and communication technologies (ICTs), to explore which ethical issues these might raise, evaluate the ethical issues and explore governance arrangements to proactively address them.

The project relied heavily on discourse analyses in order to identify the emerging technologies. These were defined as socio-technical systems that are currently perceived as being likely to significantly affect the way we live our lives within a time span of 10 to 15 years. The result of the initial identification step was a list of 11 technologies (Affective Computing, Ambient Intelligence, Artificial Intelligence, Bioelectronics, Cloud Computing, Future Internet, Human Machine Symbiosis, Neuroelectronics, Quantum Computing, Robotics, Virtual/Augmented Reality). For each of these technologies a separate review of the ICT and ethics literature was undertaken. The result was a detailed account of those ethical aspects of the different technologies. This theoretical account was then triangulated using focus groups of potential technology users and a survey of all EU ICT research project coordinators.³

The interest in the present paper is not so much on the content and findings of the project but on the way in which epistemologically problematic claims about normative aspects of emerging technologies were treated in discourse among stakeholders. In the ETICA project one could observe two attempts to

³ For a more detailed account of the project methodology see: Stahl et al. 2010.

translate the research to become relevant to the 'lifeworlds' of other stakeholders.⁴ The first translation was from research into policy recommendations. As a European research project, one of the outputs was a set of policy recommendations aimed at EU research policy makers. The ETICA project developed such recommendations in collaboration with the European Parliament's Science and Technology Options Assessment Panel (STOA). They were subsequently published as a STOA policy brief. This translation raised no practical problems, possibly because European policy makers and in particular the STOA panel are used to receiving and acting upon a variety of recommendations from numerous contributors. Put differently, the intervention was directed at recipients who engage continuously in translation between different communities of discourse, notably different scientific communities and European policy communities.

Another step which can be understood as a type of translation was also undertaken in ETICA. The ethics of emerging ICTs are likely to be relevant to most individuals in modern societies. At the same time they are highly abstract. An attempt was therefore made to translate the findings of the ETICA project using stylistic means of science fiction stories (Stahl 2013) to render the findings about the technologies as well as ethical concerns more concrete. While still published in an academic outlet, the core of the story was based on the overlapping capabilities of several of the ICTs described in ETICA. The storyline incorporated a number of the ethical issues related to emerging ICTs but tried to render them more accessible by displaying them in the form of a short story. This story is not yet published, so it is too early to discuss its success in translating uncertain claims for consideration in discourse. However, this step suggests that translated claims need to employ a vocabulary, frame of reference and concepts comprehensible to all of the stakeholders in a discourse. In the case of non-expert stakeholders, the translation of claims into lay language (or stories) may be required.

This brings us to the second example of a research project investigating ethical aspects of emerging technologies, the PHM-Ethics project.

PHM-Ethics

The aim of the PHM-Ethics project (Personal Health Monitoring Ethics, <http://ethics.p-h-m.org>, European Union GA 230602) was to explore the future development and implementation of technologies that can be applied to automated repeated or continuous collection of signs related to health status. Many of these technologies are closely related to those studied in the ETICA project. The purpose of the PHM-Ethics project was again to uncover which ethical issues might arise, and to evaluate the ethical issues. As part of the project each of the partners (which came from a variety of academic disciplines) independently analysed a selection of scenarios, producing a report based on the application of their earlier work on the project to the scenarios.⁵ In doing so each report was couched in language that was accessible to researchers from other academic backgrounds. Presentations based on

⁴ As used by Habermas, lifeworld (Lebenswelt) is a term taken from phenomenology that refers to the shared and taken for granted aspects of actors' environments (Habermas 1985, 5:186). According to Habermas, society is divided into two aspects: the 'lifeworld' and the 'system'. Communicative rationality, or discourse, occurs in the former (Finlayson 2005).

⁵ Prior to production of the report, project meetings were necessary to reconcile the epistemological stances of different disciplines.

these reports were then discussed at a project meeting in a process approaching a discourse (albeit one with inadequate representation of stakeholders to be confident the criteria of discourse ethics have been met). Although the project did not engage in an empirical discourse with a range of stakeholders affected by emerging PHM applications, uncertain claims from a variety of background disciplines needed to be translated across discipline boundaries to be comprehensible in the multidisciplinary discourse. The methods employed in PHM-Ethics suggest that awareness of the frame of reference and vocabulary familiar to stakeholders in discourse, in this case academics from a variety of background disciplines, is required for successful translation (even if that frame of reference is not accepted by those making the translation).

Conclusions

ETICA and PHM-Ethics indicate a way forward to develop the technique of translation. Unfortunately, the projects had ended before the conceptual framework described here had been fully developed. The insights into the practicalities of translation as revealed in the steps taken in ETICA and PHM-Ethics have been carried forward into an on-going research project at De Montfort University (DMU), which seeks to further develop the framework of translation described here, along with a methodology of translation grounded in discourse theory, reflective equilibrium and empirical ethics.⁶ Regardless of the success of the methodology developed in the on-going research project, the case made for reconsidering the epistemic value of uncertain normative statements used in ethical assessment of emerging technologies and anticipatory decision-making remains valid. Further research is required to confirm discourse ethics as an appropriate foundation for (a theory of) translation. The problem identified here requires further consideration because current techniques for the ethical evaluation of emerging technologies lack a clear understanding of the epistemic value of the evidence base upon which decisions are made. Translation has been suggested as a conceptual framework in which this problem can be better understood.

An epistemological problem exists with all current attempts to base policy, governance, system design and other anticipatory action on normative empirical data which is gathered under conditions of uncertainty. The foundation of this problem lies in the relationship between facts, norms and the future—if facts and norms cannot be derived from empirically observable phenomena and existing social practices (respectively), as is the case in considering the future, then they cannot be given the same epistemic value as facts and norms concerning existing phenomena. Despite this, uncertain normative claims should be taken seriously in crafting the societal response to emerging technologies, just as religious ideas should be taken seriously in political discourse. In both cases the ideas must be translated to make their epistemic value clear, and to reveal the evidence base upon which the claims rest. Normative claims about the future made by moral practitioners must be taken seriously by policy makers, but their relative value in discourse remains unclear. An account of the epistemic value and treatment of normative empirical data in discourse has been suggested as a solution. To move forward, the methodological and validity requirements of 'translation' requires further development.

⁶ The lead author can be contacted for further information or updates about the project.

This work aimed to identify an often unspoken problem in current approaches to the ethical assessment of emerging technologies, and related areas of future-oriented research which call for anticipatory action at a social and political level. The paper described a conceptual framework to establish the relative epistemic value of uncertain normative claims in discourse. In practice, the framework provides a way forward to clarify the validity of anticipatory evidence-based policy and governance which relies upon uncertain normative empirical data as evidence. Uncertain normative claims, or prescriptive statements about an inherently uncertain future, cannot have the same epistemic value or be treated analogously to scientific observations in discourse. Put another way, evidence-based policy and governance meant to prevent undesirable futures currently fails to explain the relative importance given to uncertain normative claims about the future in discourse, in comparison to prescriptive claims and scientific observations of existing phenomena. This failure is a result of lacking a conceptual framework by which the 'validity' of uncertain normative claims can be established. As such, the validity of such 'future-oriented' policy and governance is placed into doubt. The conceptual framework presented in this paper, based upon Habermas' discourse theory, provides the foundations for the development of an evaluative framework for uncertain normative claims. Put another way, our framework provides a way forward to evaluate the *relative* epistemic value of uncertain normative claims, or their 'validity' in comparison to other types of claims considered in discourse. Furthermore, our framework shows that researchers *can* base reasonable validity claims on normative empirical research on the ethics of emerging technologies *while uncertainty still prevails*. Anticipatory evidence-based policy making and governance should therefore take heed of normative empirical data about the future, and take it seriously alongside other types of (observational) evidence in political discourse.

The point of this paper was not to provide a definitive account of the relative epistemic value of uncertain normative statements, or a comprehensive set of evaluative criteria by which they may be judged. The debate over the appropriate criteria for evaluating uncertain normative considerations is on-going, and applies to all types of ethical assessments of future states (Grunwald 2009), not just translation. Rather, we have aimed to show that it is reasonable to take uncertain normative claims seriously in discourse through analogy with religious beliefs in political discourse. The approach in this paper attaches the legitimacy of such claims to discourse ethics, which suggests that the TCA's principles of validity can provide a theoretical foundation for evaluation under conditions of uncertainty. Although the requirements of successful translation still need to be worked out through the development of a full methodology, the first steps have been taken here in making the case for discourse theory and translation as a legitimate conceptualisation and solution to a previously unrecognised epistemological problem in evidence-based policy making.

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Appendix 19: NRES Approval Letter



Health Research Authority

NRES Committee East Midlands - Leicester

The Old Chapel
Royal Standard Place
Nottingham
NG1 6FS

Telephone: 0115 8839425
Facsimile: 0115 8839294

30 May 2012

Brent Mittelstadt
Research Student
De Montfort University
Gateway House 5.74
The Gateway
De Montfort University
LE1 9BH

Dear Mittelstadt,

Study title: Qualitative study regarding perceptions of Personal Health Monitoring involving diabetes and hypertension patients, their GPs/specialists, and NHS managers responsible for care commissioning and public health advocacy.

REC reference: 12/EM/0160

Thank you for your letter of 29 May 2012, responding to the Committee's request for further information on the above research and submitting revised documentation.

The further information has been considered on behalf of the Committee by the Chair.

Confirmation of ethical opinion

On behalf of the Committee, I am pleased to confirm a favourable ethical opinion for the above research on the basis described in the application form, protocol and supporting documentation as revised, subject to the conditions specified below.

Ethical review of research sites

NHS sites

The favourable opinion applies to all NHS sites taking part in the study, subject to management permission being obtained from the NHS/HSC R&D office prior to the start of the study (see "Conditions of the favourable opinion" below).

Non-NHS sites

Conditions of the favourable opinion

The favourable opinion is subject to the following conditions being met prior to the start of the study.

Management permission or approval must be obtained from each host organisation prior to the start of the study at the site concerned.

Management permission ("R&D approval") should be sought from all NHS organisations involved in the study in accordance with NHS research governance arrangements.

Guidance on applying for NHS permission for research is available in the Integrated Research Application System or at <http://www.rdforum.nhs.uk>.

Where a NHS organisation's role in the study is limited to identifying and referring potential participants to research sites ("participant identification centre"), guidance should be sought from the R&D office on the information it requires to give permission for this activity.

For non-NHS sites, site management permission should be obtained in accordance with the procedures of the relevant host organisation.

Sponsors are not required to notify the Committee of approvals from host organisations

It is the responsibility of the sponsor to ensure that all the conditions are complied with before the start of the study or its initiation at a particular site (as applicable).

Approved documents

The final list of documents reviewed and approved by the Committee is as follows:

<i>Document</i>	<i>Version</i>	<i>Date</i>
Covering Letter		29 March 2012
Evidence of insurance or indemnity		07 July 2011
Interview Schedules/Topic Guides: Patients - Diabetes	1.0	07 March 2012
Interview Schedules/Topic Guides: Patients - Hypertension	1.0	07 March 2012
Interview Schedules/Topic Guides: GP - Dementia	1.0	07 March 2012
Interview Schedules/Topic Guides: GP - Diabetes	1.0	07 March 2012
Interview Schedules/Topic Guides: GP - Hypertension	1.0	07 March 2012
Interview Schedules/Topic Guides: NHS Managers - Care Commissioner	1.0	07 March 2012
Interview Schedules/Topic Guides: NHS Managers - Public Health Advocate	1.0	07 March 2012
Investigator's Brochure		29 March 2012
Letter of invitation to participant: Local Collaborator - Dr Stephen Jackson	1.0	10 February 2012
Letter of invitation to participant: Local Collaborator - Dr Adrian Stanley	1.0	21 July 2011
Letter of invitation to participant: NHS Managers - Public Health Advocates	3.0	07 March 2012
Letter of invitation to participant: NHS Managers - Care Commissioners	3.0	07 March 2012
Letter of invitation to participant: GP - Hypertension	3.0	07 March 2012
Letter of invitation to participant: GP - Diabetes	3.0	07 March 2012
Letter of invitation to participant: GP - Dementia	3.0	07 March 2012
Letter of invitation to participant: Patients - Diabetes	3.0	07 March 2012
Other: Unfavourable letter for study reference 11/EM/0352		19 October 2011
Other: Invalid letter for study reference 12/EM/0064		24 January 2012
Other: CV - Dr Fairweather		08 March 2012
Other: CV - Mark Shaw		

Other: CV - Neil McBride		08 March 2012
Other: Registration Form		08 September 2011
Participant Consent Form: GP - Dementia	3.0	07 March 2012
Participant Consent Form: GP - Diabetes	3.0	07 March 2012
Participant Consent Form: GP - Hypertension	3.0	07 March 2012
Participant Consent Form: NHS Managers - Care Commissioner	3.0	07 March 2012
Participant Consent Form: NHS Managers - Public Health Advocate	3.0	07 March 2012
Participant Consent Form: Patients - Diabetes	4.0	25 May 2012
Participant Consent Form: Patients - Hypertension	4.0	25 May 2012
Participant Information Sheet: GP - Dementia	3.0	07 March 2012
Participant Information Sheet: GP - Diabetes	3.0	07 March 2012
Participant Information Sheet: GP - Hypertension	3.0	07 March 2012
Participant Information Sheet: NHS Managers - Care Commissioner	3.0	07 March 2012
Participant Information Sheet: NHS Managers - Public Health Advocate	3.0	07 March 2012
Participant Information Sheet: Local Collaborator - Dr Stephen Jackson	3.0	07 March 2012
Participant Information Sheet: Local Collaborator - Dr Adrian Stanley	3.0	07 March 2012
Participant Information Sheet: Patients - Diabetes	4.0	25 May 2012
Participant Information Sheet: Patients - Hypertension	4.0	25 May 2012
Protocol	3.0	07 March 2012
REC application	103621/309173/1/891	29 March 2012
Response to Request for Further Information		29 May 2012

Statement of compliance

The Committee is constituted in accordance with the Governance Arrangements for Research Ethics Committees and complies fully with the Standard Operating Procedures for Research Ethics Committees in the UK.

After ethical review

Reporting requirements

The attached document "*After ethical review – guidance for researchers*" gives detailed guidance on reporting requirements for studies with a favourable opinion, including:

- Notifying substantial amendments
- Adding new sites and investigators
- Notification of serious breaches of the protocol
- Progress and safety reports
- Notifying the end of the study

The NRES website also provides guidance on these topics, which is updated in the light of changes in reporting requirements or procedures.

Feedback

You are invited to give your view of the service that you have received from the National

Research Ethics Service and the application procedure. If you wish to make your views known please use the feedback form available on the website.

Further information is available at National Research Ethics Service website > After Review

12/EM/0160

Please quote this number on all correspondence

With the Committee's best wishes for the success of this project

Yours sincerely

A handwritten signature in black ink, appearing to read 'Dr Carl Edwards'.

Dr Carl Edwards
Chair

Email: jessica.parfremment@nottspct.nhs.uk

Enclosures:

"After ethical review – guidance for researchers"

Copy to:

Sponsor - Jan Hewitt

R&D Contact - Lisa Wann